HTA Austria
Austrian Institute for
Health Technology Assessment
GmbH

Health Economic Reference Cases and Costing Approaches

Concepts, International Practices and Implications for Austria

Final report

AIHTA Project Report No.: 174 | ISSN: 1993-0488 | ISSN-online: 1993-0496

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Vienna, March 2026

Project Team

Project leader:	Christoph Strohmaier, MSc
Authors:	Christoph Strohmaier, MSc Judit Erdös, MA

Project Support

Hand search:	Christoph Strohmaier, MSc
Internal review:	Dr.in rer. soc. oec. Ingrid Zechmeister-Koss, MA
External review:	Assoc.-Prof.in MMag.a Dr.in Susanne Mayer, Associate Professor, Deputy Head of Department of Health Economics, Centre for Public Health, Medical University of Vienna

Correspondence: Christoph Strohmaier, christoph.strohmaier@aihta.at

Cover photo: @ oatawa – stock.adobe.com

This Study was supported by:

Parts of the text were linguistically supported using AI-based writing tools; all substantive content was verified by the authors

This report should be referenced as follows:

Strohmaier C., Erdös, J. Health Economic Reference Cases and Costing Approaches: Concepts, International Practices and Implications for Austria. AIHTA Project Report No.: 174; 2026. Vienna: HTA Austria – Austrian Institute for Health Technology Assessment GmbH.

Conflict of interest

All authors and the reviewers involved in the production of this report have declared they have no conflicts of interest in relation to the technology assessed according to the Uniform Requirements of Manuscripts Statement of Medical Journal Editors (www.icmje.org).

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IMPRINT

Publisher:
HTA Austria – Austrian Institute for Health Technology Assessment GmbH
Josefstädter Straße 39 | 1080 Vienna – Austria
https://www.aihta.at/

Responsible for content:
Dr. rer. soc. oec. Ingrid Zechmeister-Koss, MA, managing director

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AIHTA Project Reports are only available to the public via the Internet at http://eprints.aihta.at/view/types/hta_report.html.

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ISSN online 1993-0496

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List of abbreviations

ACFI ..... Aged Care Funding Instrument
ADL ..... Activities of Daily Living
AR-DRG ..... Australian Refined Diagnosis Related Groups
ARPs..... Alternative Payment Plans
ASP..... Average Sales Price
ATIH..... Agence Technique de l'Information sur l'Hospitalisation / Technical Agency for Hospital Information
AUS ..... Australia
BA..... Bundesagentur für Arbeit
BCFI..... Belgian Centre for Pharmacotherapeutic Information
BEL ..... Belgium
BIA ..... Budget Impact Analysis
BIAG ..... Budget Impact Analysis Guideline(s)
BNF..... British National Formulary
CA..... Cost Analysis / Cost-Analysis
CADTH ..... Canadian Agency for Drugs and Technologies in Health
CAN ..... Canada
CBA..... Cost-Benefit Analysis
CC ..... Cost-Comparison
CCA..... Cost-Consequence Analysis / Cost-Consequences Analysis
CEA..... Cost-Effectiveness Analysis
CEAC ..... Cost-Effectiveness Acceptability Curve
CEACs ..... Cost-Effectiveness Acceptability Curves
CHEERS..... Consolidated Health Economic Evaluation Reporting Standards
CHSP ..... Commonwealth Home Support Programme
CM..... Costing Manual(s)
CMA..... Cost-Minimisation Analysis

CMG ..... Case-Mix Group
CMI ..... Case Mix Index
CPI ..... Consumer Price Index
CT ..... Computertomographie / Computed Tomography
CUA ..... Cost-Utility Analysis
CVB ..... Centraal Bureau voor de Statistiek
DAGS ..... Ambulante Gruppierungssysteme (Dänemark) / Danish Ambulatory Grouping System
DCEA ..... Distributional Cost-Effectiveness Analysis
DDD ..... Defined Daily Dose
DESDE ..... Description and Evaluation of Services and Directories
DHE ..... Department of Health Economics
DKN ..... Denmark
DMC ..... Danish Ministry of Finance's Centre for Economic Evaluation / Danish Medicines Council
DRG ..... Diagnosis Related Group
DSA ..... Deterministic Sensitivity Analysis
DTC ..... Diagnosis Treatment Combination
E&W ..... England & Wales
EbM ..... Evidence-basierte Medizin
EBM ..... Evidence-Based Medicine
EKO ..... Erstattungskodex
EMA ..... European Medicines Agency
eMIT ..... Drugs and Pharmaceutical Electronic Market Information Tool
EPAR ..... European Public Assessment Report
EU ..... European Union
EUnetHTA ..... European Network for Health Technology Assessment
EVPI ..... Expected Value of Perfect Information
EVPPI ..... Expected Value of Partial Perfect Information
FCA ..... Friction Cost Approach
FCR ..... Follow-up Care and Rehabilitation
FPS ..... Federal Public Service
FRA ..... France
GDP ..... Gross Domestic Product
GEAR ..... Guide to Economic Analysis and Research
GER ..... Germany
GIP ..... Genees- en hulpmiddelen Informatie Project
GP ..... General Practitioner
HAH ..... Hospitalisation at Home
HAS ..... French National Authority for Health
HCA ..... Human Capital Approach
HCUP ..... Healthcare Cost and Utilization Project
HE ..... Health Economics
HEA ..... Health Economic Analysis / Health Economic Analyses

HEE ..... Health Economic Evaluation(s)
HEEG ..... Health Economic Evaluation Guideline(s)
HELFO ..... Norwegian Health Economics Administration
HICP ..... Harmonised Index of Consumer Prices
HPG ..... Homogeneous Patient Group(s)
HQIP ..... Healthcare Quality Improvement Partnership
HRG ..... Healthcare Resource Group
HRQoL ..... Health-Related Quality of Life
HTA ..... Health Technology Assessment
HTAG ..... Health Technology Assessment Guideline(s)
iCARE ..... Instrument zur Messung von Kosten und Ressourcenverbrauch in der Pflege
ICER ..... Incremental Cost-Effectiveness Ratio / Institute for Clinical and Economic Review
ICU ..... Intensive Care Unit
IFA ..... Informationsstelle für Arzneispezialitäten
IMA–AIM ..... Intermutualistisch Agentschap – Agence Intermutualiste / InterMutualist Agency
InEK ..... Institut für das Entgeltsystem im Krankenhaus
iPCQ ..... iMTA Productivity Cost Questionnaire
IQWiG ..... Institut für Qualität und Wirtschaftlichkeit im Gesundheitswesen
ISPOR ..... The Professional Society for Health Economics and Outcomes Research
iVICQ ..... iMTA Valuation of Informal Care Questionnaire
KCE ..... Belgian Health Care Knowledge Centre
LGA ..... Local Government Association
LKF ..... Leistungsorientierte Krankenanstaltenfinanzierung
LPPR ..... Liste des Produits et Prestations Remboursables
MBS ..... Medicare Benefits Schedule / Medical Benefit Scheme
MC ..... Marginal Cost
MEA ..... Managed Entry Agreement
MPSC ..... Medicines Procurement and Supply Chain
MRI ..... Magnetresonanztomographie / Magnetic Resonance Imaging
MSO ..... Médecine, Chirurgie, Obstétrique et Odontologie
MZG-RHM ..... Minimale Ziekenhuisgegevens – Résumé Hospitalier Minimum / Minimum Hospital Data
NCC ..... National Cost Collection
NCS ..... Nationale Kostenstudie / National Cost Study
NHCDC ..... National Hospital Cost Data Collection
NHS ..... National Health Service
NICE ..... National Institute for Health and Care Excellence
NLD ..... The Netherlands
NMA ..... Norwegian Medical Association
NoMA ..... Norwegian Medicines Agency / Norwegian Medical Products Agency
NOR ..... Norway
NPSCW ..... National Public Sector Cost Weights
NZa ..... Nederlandse Zorgautoriteit
NZL ..... New Zealand

OOP..... Out-of-Pocket / Out-of-Pocket Payments
OTC..... Over-the-Counter
PAS..... Patient Access Scheme
PBAC ..... Pharmaceutical Benefits Advisory Committee
PBS..... Pharmaceutical Benefits Scheme / Pharmaceutical Benefit scheme
PCE ..... Patient Cost Estimator
PCE-H..... Personal Consumption Expenditures for Healthcare
PECUNIA..... ProgrammE in Costing, resource use measurement and outcome valuation for Use in multi-sectoral National and International health economic evaluAtions
PEPP ..... Pauschalierendes Entgeltsystem für Psychiatrie und Psychosomatik
PFS..... Physician Fee Schedule
PHARMAC..... Pharmaceutical Management Agency
PICo ..... Population, Interest, Context
PLICS ..... Patient-Level Information and Costing System
PMSI MSO ..... The Medical IT system for Medicine, Surgery, Obstetrics and Odontology
PMSI ..... Programme de Médicalisation des Systèmes d'Information
PoMS..... Prescription Only Medicines
PPP..... Purchasing Power Parity
PSA..... Probabilistic Sensitivity Analysis
PSS ..... Personal Social Services
PSSRU ..... Personal Social Services Research Unit
PU..... Purchase Unit
QALY ..... Quality-Adjusted Life Year
RCT..... Randomised Controlled Trial
RIW..... Resource Intensity Weight
RIZIV – INAMI ..... Rijksinstituut voor Ziekte- en Invaliditeitsverzekering – Institut National d'Assurance Maladie-Invalidité
RPDC..... Routine Practice Data Collection / Routine Practice Data Collection from Registries
RQ ..... Research Question
RTC..... Reference List of Unit Costs / French Unit Cost Lists
RUC ..... Resource Unit Cost / Reference Unit Cost
RUG-III ..... Resource Utilisation Groups Version III
RWD ..... Real-World Data
SACT..... Systemic Anti-Cancer Therapy
SAE..... Statistique Annuelle des Établissements de santé / Annual Statistics of Healthcare Institutions
SCT ..... Scotland
SHI ..... Social Health Insurance
sIMPL ..... databank van implantaten
SMC ..... Scottish Medicines Consortium
SNDS ..... Système National des Données de Santé / National Health Data System
SNIIRAM..... Système National d'Information Inter-Régimes de l'Assurance Maladie / National Health Insurance Statistics Data
SR..... Systematic Review

TC ..... Total Costs / Total Cost
TCT ..... Technical Cell for the processing of hospital data / Technical Unit for the Processing of Data relating to Hospitals
TFR ..... Tarif Forfaitaire de Responsabilité
TNB ..... Table Nationale de Biologie
UK ..... United Kingdom
UKHSA ..... UK Health Security Agency
URG ..... Urgency Related Group
USA ..... United States of America
VAT ..... Value Added Tax / Value-Added Tax
VOI ..... Value of Information
VWS ..... Ministerie van Volksgezondheid, Welzijn en Sport
WHO ..... World Health Organisation
WIdO ..... Wissenschaftliches Institut der AOK
WMG ..... Wet marktordening gezondheidszorg
WPAI ..... Work Productivity and Activity Impairment Questionnaire
ZIN ..... Zorginstituut Nederland

Executive Summary

Background

Reliable cost and resource data are essential for health technology assessment (HTA) and sustainable healthcare planning. This requires a robust costing process.

Several healthcare systems, such as those in the United Kingdom and the Netherlands, provide national health economic guidelines with standardised reference cases and costing processes. These define core methodological principles to ensure comparability across studies and technologies, often operationalised through national cost collections with unit costs or tariffs.

In Austria, valuable foundations exist, including the DHE Unit Cost Online Database and tools from the EU-funded PECUNIA project. However, a key challenge remains: the lack of consensus on national reference methods and standardised costing approaches.

Objectives

This project provides an overview of international reference methods and costing approaches to inform future Austrian guidelines, particularly for HTA of high-cost hospital pharmaceuticals. The report aims to:

- Present fundamental costing concepts and methods
- Compare international best practices in reference cases and costing processes
- Derive transferable principles for a future Austrian guideline

Methods

The report analyses health economic guidelines, HTA guidelines, budget impact analysis guidelines, costing manuals, and relevant HTA agency documents from multiple countries, with a specific focus on costing processes. A multi-stage approach was implemented: starting from the ISPOR guideline overview, supplemented by systematic reviews. Countries with detailed costing information in their guidelines (German or English) were included. In total, 72 documents from 59 countries were screened. Data extraction covered reference case characteristics and detailed costing processes, followed by narrative and tabular synthesis.

Results

Costing Fundamentals

Costing comprises three steps: identification (“what?”), measurement (“how much?”), and valuation (“at what price?”). The chosen perspective fundamentally determines which costs are included – ranging from the patient perspective through healthcare payer perspective to the comprehensive societal perspective, considered the scientific gold standard.

Traditionally, costs are functionally classified into direct costs (healthcare and non-healthcare), indirect costs (productivity losses), and intangible costs (pain, suffering). The newer sectoral classification system

explicitly distinguishes where costs occur (health sector, education, justice, labour market, patient/family), offering greater decision-maker relevance.

Costing approaches are defined by two axes: level of detail (macro- vs. micro-costing) and calculation direction (top-down vs. bottom-up), creating four approaches with different feasibility-accuracy trade-offs. Bottom-up micro-costing, the gold standard, captures each input with actual quantities and prices – highest precision but data-intensive. Top-down macro-costing is quicker but more imprecise.

Quality criteria for costing include completeness, directness, and realism in identification; accuracy, precision, and transparency in measurement; and transparency, credibility, and realism in valuation. Overarching criteria such as uncertainty analysis, reliability, and transferability ensure scientific quality.

International Reference Methods and Costing Processes

Guidelines from 12 countries fulfilled our inclusion criteria. All 12 countries demonstrate well developed methodological standards. Six have dedicated costing manuals. Compliance is mandatory in most cases.

There is consensus on overarching core principles, such as the preference for cost-utility analyses and the conduct of uncertainty analyses to test the robustness of cost calculations. Differences emerge in discount rates and the detailed cost assessment process, reflecting national preferences, economic priorities, and the respective healthcare system structure.

Resource Identification

While bottom-up micro-costing is the gold standard, most countries adopt a pragmatic "fit-for-purpose" approach with top-down macro-costing. The Netherlands deviates with a "micro-costing-first" principle, challenging the feasibility-accuracy trade-off premise.

Three perspective clusters emerge:

- Strict healthcare perspective (Australia, Belgium, Canada, England & Wales, New Zealand, Scotland, USA): Focus on public healthcare system costs
- Social health insurance perspective (Germany): Hybrid including patient co-payments and work absence costs
- Societal perspective (Denmark, France, Netherlands, Norway): Most comprehensive, including direct non-healthcare costs, informal care, and productivity costs

The most significant divergence concerns cross-sectoral costs. The Netherlands uniquely operationalises societal perspective by formally including impacts on education and justice sectors.

Resource Measurement

High harmonisation exists for core health service domains. The most universal trend is reliance on diagnosis-related groups for inpatient episodes. Almost every guideline emphasises local data adaptation. Germany and the Netherlands set standards for methodological rigor with highly structured evidence retrieval processes.

Resource Valuation

Valuation is strongly tied to national cost data to ensure local relevance. Most countries pragmatically use national tariffs and fees. The Netherlands, Scotland, and France increasingly pursue true economic resource valuation to capture long-term opportunity costs.

Key findings by healthcare (service) domain:

- Non-inpatient services: Universally based on national data, but methodological depth varies. New Zealand, Norway, and Canada attempt more precise resource capture.

- Pharmaceuticals: All countries use official databases, but approaches to confidential discounts diverge. England & Wales use list prices publicly and discounted prices in confidential decision-making.
- Medical devices: Split between bundled service-based and detailed product-based approaches. New Zealand's life-cycle costing model represents methodological progress.
- Hospital services: Strong consensus on diagnosis-related groups. Canada and the Netherlands offer multi-layered approaches adaptable to decision context.
- Residential care, home nursing, and home care: Internationally inconsistent; only Australia, Canada, and Denmark have developed specific methodologies.
- Transport and travel: Clear perspective indicator – included in Denmark, Norway, Netherlands; excluded in Belgium, Scotland.
- Productivity costs, patient time, informal care: Mostly excluded. Germany and Netherlands include productivity costs with friction cost approach preferred. Distinction between productivity costs and patient time is methodologically fundamental.
- Other services (e.g., community and other social services): Systematically captured only by Netherlands, Denmark, Canada.
- Cross-sectoral costs: Universally excluded except Netherlands.
- Overhead costs: Mostly implicit; explicit methods only in Canada and Netherlands.

Discussion

The analysis reveals a high level of methodological maturity with commonalities – long-term time horizons, application of uncertainty analyses, use of local data – alongside significant differences shaped by governance, political priorities, data availability and underlying philosophies. The most significant divergence concerns the purpose and feasibility of costing – pragmatic versus precision-oriented paradigms.

Perspective choice is the most consequential decision, determining included costs, their quantification and valuation. Costing processes are fundamentally shaped by data infrastructure: systems with rich administrative data enable more detailed methods; fragmented systems rely on pragmatic approaches.

For Austria, explicit decisions are required on:

- Perspective: Healthcare, societal, or hybrid perspective with clear positions on productivity costs, patient/caregiver time, and cross-sectoral costs
- Costing approach: Balance between micro-costing ideal and pragmatic framework – a mixed approach with micro-costing for high-impact technologies is recommended
- Further aspects: Tariff versus opportunity costs, medical device valuation, productivity cost methodology, confidential discounts, exclusion of transfers and intangible costs

Limitations of this report include that the analysis is based on an exploratory hand search, is restricted to German- and English-language guidelines, and that the actual application of the principles in practice was not verified.

Conclusion

The analysis of international guidelines and costing manuals reveals methodological flexibility for Austria. Perspective choice and definition of relevant costs are central decisions with political character. This report provides a framework for a future Austrian reference case and costing process to be embedded in health economic guidelines. Next steps include analysis of Austrian cost data sources (LKF system, reimbursement code, DHE database) and development of an Austrian reference case within a guideline development process.

Zusammenfassung

Hintergrund

Zuverlässige Kosten- und Ressourcendaten sind für die Bewertung von Gesundheitstechnologien und nachhaltige Systemplanung unerlässlich. Grundlage dafür ist die Kostenerfassung (engl. Costing), die einen wesentlichen Bestandteil gesundheitsökonomischer Evaluationen darstellt.

Länder wie das Vereinigte Königreich und die Niederlande stellen durch nationale Leitlinien Referenzmethoden (engl. Reference Cases) mit standardisierten Kostenerfassungsprozessen und Kostendatensammlungen (engl. Cost Collections) inklusive Einheitskosten (engl. Unit Costs) für unterschiedliche Leistungen bereit, die Vergleichbarkeit der Kosten zwischen Studien und bewerteten Technologien gewährleisten.

In Österreich bieten die „DHE Unit Cost Online Database" der Medizinischen Universität Wien und das EU-geförderte PECUNIA-Projekt eine wertvolle Basis. Es fehlen jedoch nationale gesundheitsökonomische Leitlinien und ein Konsens über an den österreichischen Kontext angepasste standardisierte Methoden für alle Phasen der Kostenerfassung.

Problemstellung und Ziele

Dieser Bericht gibt einen Überblick über internationale Kostenerfassungsansätze. Es legt damit eine Grundlage für die Ausgestaltung der Kostenerfassung in einer künftigen nationalen Leitlinie und fokussiert auf die Anwendung für konkrete österreichische Bewertungsprozesse, wie etwa im Kontext von Health Technology Assessments (HTA) für hochpreisige Arzneimittel im stationären Bereich.

Der Bericht adressiert drei Fragen:

- Was sind die grundlegenden Konzepte und Methoden der Kostenerfassung?
- Welche Best Practices und Methoden zu Kostenerfassungs-Prozessen werden in internationalen Leitlinien vorgegeben?
- Welche Anhaltspunkte lassen sich für eine künftige österreichische Leitlinie ableiten?

Methoden

Der Bericht analysiert gesundheitsökonomische Leitlinien, HTA-Leitlinien sowie verwandte Dokumente aus mehreren Ländern mit Fokus auf den Kostenerfassungs-Prozess.

Zur ersten Forschungsfrage wurden die Grundlagen der Kostenerfassung – konzeptionelle Basis, Prozessschritte und Qualitätskriterien auf Basis internationaler Standards – dargestellt. Für die zweite Forschungsfrage wurden ausgehend vom ISPOR-Leitlinienüberblick insgesamt 72 Dokumente aus 59 Ländern gesichtet. Aus jenen, die vorab festgelegten Einschlusskriterien entsprachen, wurden Informationen zu Kostenerfassungsprozessen und Methoden im Detail extrahiert. Die Auswertung erfolgte narrativ und tabellarisch. Zur dritten Forschungsfrage wurden die Ergebnisse zusammengefasst und in den österreichischen Kontext eingeordnet, um eine künftige nationale Referenzmethode zu informieren.

Ergebnisse

Grundlagen der Kostenerfassung

Die Kostenerfassung umfasst die Identifikation („Was?“), Messung („Wie viel?“) und Bewertung („zu welchem Preis?“) von Ressourcen und ist grundlegend für gesundheitsökonomische Evaluationen. Die gewählte Perspektive bestimmt, welche Kosten einbezogen werden – von der Patient:innenperspektive

über die Gesundheitsbudgetperspektive bis zur gesellschaftlichen Perspektive als Goldstandard. Kosten werden traditionell in direkte, indirekte und immaterielle Kosten eingeteilt. Das neuere sektorale Klassifikationssystem unterscheidet explizit Sektoren, wo die Kosten anfallen (z.B. Gesundheitssektor, Bildung, Justiz oder Arbeitsmarkt). Es folgt somit der Budgetlogik und gilt als entscheidungsträgerfreundlicher.

Die Kostenermittlung spannt sich zwischen Detaillierungsgrad (Makro- vs. Mikro-Costing) und Berechnungsrichtung (Top-Down vs. Bottom-Up) auf. Bottom-Up Mikro-Costing erfasst jeden Input mit tatsächlichen Mengen und Preisen und gilt als Goldstandard, ist jedoch aufwändig. Top-Down Makro-Costing ist schnell, aber unpräziser. Qualitätskriterien wie Vollständigkeit, Transparenz und Glaubwürdigkeit der Quellen sichern die wissenschaftliche Qualität in jeder Phase.

Internationale Referenzmethoden und Kostenerfassungs-Prozesse

Leitlinien aus 12 Ländern entsprachen unseren Einschlusskriterien. Alle 12 Länder weisen ausgereifte methodische Standards auf. Sechs verfügen über ein eigenes Kostenerfassungs-Manual. Die Einhaltung der Leitlinien ist in den meisten Ländern für Einreichungen bei nationalen Behörden verpflichtend. Während Länder wie Australien, Dänemark, Neuseeland und Schottland primär arzneimittelbezogene Leitlinien entwickelt haben, verfolgen andere ein technologie-unabhängiges Framework.

Zu übergeordneten Kernprinzipien wie die Präferenz für Kosten-Nutzwert-Analysen (engl. Cost-Utility-Analysis) und Durchführung von Unsicherheitsanalysen, um die Robustheit der Kostenberechnung zu prüfen, besteht Konsens. Unterschiede zeigen sich bei den Diskontierungsraten sowie im detaillierten Kostenerfassungs-Prozess. Sie spiegeln nationale Präferenzen, wirtschaftliche Prioritäten und die jeweilige Gesundheitssystemstruktur wider.

Identifikation von Ressourcen

Obwohl Bottom-up-Mikro-Costing als Goldstandard gilt, verfolgen die meisten Länder einen pragmatischen Top-down-Makro-Costing-Ansatz. Mikro-Costing bleibt Situationen mit höherem Genauigkeitsbedarf vorbehalten. Die Niederlande bilden mit ihrem „Mikrokosten-First-Prinzip“ eine Ausnahme.

Bei der Perspektive lassen sich drei Gruppen unterscheiden: Eine strenge Gesundheitswesen-Perspektive (u. a. Australien, England & Wales, Kanada). Diese schließt Patient:innenkosten und Produktivitätsverluste aus. Deutschland verfolgt eine hybride GKV-Perspektive. Diese schließt Patient:innenzuzahlungen und Arbeitsunfähigkeit ein, nicht jedoch Verluste durch vorzeitigen Tod und Fahrzeiten. Dänemark, Frankreich, Norwegen und die Niederlande wählen die gesellschaftliche Perspektive, die insbesondere auch Kosten informeller Pflege und Produktivitätsverluste berücksichtigt, wobei die Niederlande als einziges Land auch Kosten in anderen Sektoren wie Bildung und Justiz einbeziehen.

Direkte medizinische Kosten über den gesamten – auch zukünftigen – Behandlungspfad sind überall eingeschlossen. Der Umgang mit nicht-medizinischen direkten Kosten und Produktivitätskosten variiert hingegen erheblich – ein Konsens fehlt. Ebenso divergieren die Länder bei der Frage, ob unabhängige zukünftige medizinische Kosten während gewonnener Lebensjahre einzubeziehen sind.

Messung von Ressourcen

Für zentrale Gesundheitsleistungen wie ambulante Versorgung, Pharmazeutika und stationäre Leistungen besteht ein hohes Maß an Harmonisierung bei der Quantifizierung der Ressourcen. Stationäre Episoden werden überwiegend über Fallpauschalsystemen (z. B. DRGs) gemessen, was länderübergreifende Vergleiche erleichtert. Mehrere Leitlinien schreiben zudem die Erfassung von Medikamentenverschwendung vor.

Fast alle Leitlinien betonen die Verwendung lokaler Daten. Expert:innenmeinungen werden hierbei nur akzeptiert, um empirische Datenlücken zu füllen. Deutschland und die Niederlande setzen mit hochstrukturierten Prozessen, die sich an der Hierarchie von Evidenz orientieren, den Maßstab für methodische Strenge und Transparenz.

Bewertung von Ressourcen

Die Ressourcenbewertung ist stark kontextabhängig und an nationale Kostendaten gebunden, um die nationale Relevanz der ökonomischen Evaluation sicherzustellen. Die meisten Länder verwenden pragmatisch nationale Stückkosten (engl. Unit Costs) und Tarife. Die Niederlande, Schottland und Frankreich streben hingegen bei den Stückkosten eine genauere Abbildung des tatsächlichen wirtschaftlichen Ressourcenverbrauchs, bspw. durch Mikrokostenstudien, an.

Ambulante Leistungen werden überwiegend über nationale Tarife oder Gebühren bewertet. Ausnahmen sind Neuseeland, Norwegen und Kanada, die wesentlich präzisere Methoden zur Bewertung einsetzen. Bei Arzneimitteln greifen alle Länder auf nationale Datenbanken zurück, unterscheiden sich jedoch im Umgang mit vertraulichen Rabatten und Einbeziehung von einrichtungsspezifischen Preisen und Kosten, die zusätzlich zu den reinen Arzneimittelkosten anfallen. Für erstattete Arzneimittel wird meist die Verwendung offizieller Datenbanken verlangt. Neuartige, nicht erstattete und Over-the-Counter-Arzneimittel sollen hingegen mittels Listen- oder Marktpreise dargestellt werden. Bei Medizinprodukten reichen die Vorgaben von der Verwendung einfacher gebündelter Ansätze auf Basis von DRGs bis hin zu detaillierten produktbasierten Bewertungsansätze. Neuseelands Lebenszykluskostenmodell, das neben dem Anschaffungspreis die gesamte Ressourcenwirkung eines Medizinprodukts berücksichtigt, bietet hierfür den methodisch fortschrittlichsten Ansatz. Für Krankenhausleistungen besteht weitgehend Konsens zur Verwendung von Fallpauschalen, ergänzt durch Tages- und Fallsätze.

Die Bewertung von Ressourcen für stationäre und häusliche Pflege ist methodisch unterentwickelt. Nur Australien, Kanada und Dänemark haben explizite Ansätze. Transportkosten werden nur in Ländern mit gesellschaftlicher Perspektive (Dänemark, Norwegen, Niederlande) systematisch einbezogen. Ausnahmen sind explizit angeführte Methoden zur Kalkulation von Rettungsdiensten in Australien und Kanada. Produktivitätskosten und informelle Pflege werden mehrheitlich ausgeschlossen. Wo erstere einbezogen werden, überwiegt der Friction-Cost-Ansatz. Patient:innenzeit wird getrennt von Produktivitätsverlusten betrachtet und in einigen Ländern (Dänemark, Norwegen) explizit erfasst.

Bei sektorübergreifenden Kosten sind die Niederlande das einzige Land mit expliziter Bewertungsmethodik für Bereiche wie Bildung und Justiz. Gemeinkosten werden meist implizit über nationale Kostensammlungen abgedeckt. Nur Kanada und die Niederlande bieten explizite methodische Anleitung. Auch kommunale Leistungen außerhalb des engeren Gesundheitssystems und soziale Dienste werden nur in wenigen Ländern (z.B. Niederlande, Dänemark, Kanada) systematisch bewertet.

Diskussion

Die Analyse zeigt einen hohen methodischen Entwicklungsstand mit Gemeinsamkeiten bei allgemeinen methodischen Prinzipien– lange Zeithorizonte, Anwendung von Unsicherheitsanalysen, Verwendung lokaler Daten – bei gleichzeitig bedeutenden Unterschieden im Detail, die durch Governance, politische Prioritäten und Datenverfügbarkeit geprägt sind.

Der wesentlichste Unterschied betrifft die Perspektive: Sie reicht von einer engen Gesundheitsbudget- bis zu umfassenden gesellschaftlichen Perspektiven und beeinflusst, welche Kosten einbezogen, wie sie quantifiziert und bewertet werden und wie das Kosten-Wirksamkeits-Verhältnis einer Technologie beurteilt wird. Der Ausschluss von Kosten außerhalb des Gesundheitssystems führt zu Verzerrungen, wenn Erkrankungen, deren Prävention oder Behandlung deutliche Ressourcenimplikationen in anderen Sektoren haben. Auch der Ausschluss informeller Pflege ist aus volkswirtschaftlicher Sicht verzerrend, da diese einen erheblichen wirtschaftlichen Wert darstellt.

Daneben besteht ein Spannungsfeld zwischen dem mehrheitlich angewendeten pragmatischen Top-down-Makro-Costing und dem präzisionsorientierten Mikrokosten-First-Prinzip der Niederlande. Der Unterschied in der Granularität der Kalkulation ist entscheidend, da er die berichtete Kosteneffektivität von Interventionen erheblich beeinflussen und potenziell zu divergierenden Erstattungsentscheidungen für neuartige Interventionen führen kann. Besonders deutlich wird das bei der unterschiedlich präzisen

Kostenerfassung ambulanter Leistungen, die zu Verzerrung von Entscheidungen in der Primärversorgung, bei der Erstattung diagnostischer Tests oder Disease-Management-Programmen führen kann.

Für Österreich sind daher explizite Entscheidungen erforderlich: zur Perspektive (Gesundheits-, Gesellschafts- oder Hybridperspektive), zum Kostenbewertungsansatz (empfohlen wird Mikro-Costing für kostenintensive Technologien) sowie zu weiteren Aspekten wie Tarif- vs. Opportunitätskosten, Medizinproduktebewertung, Produktivitätskostenmethodik und dem Umgang mit vertraulichen Rabatten.

Limitationen dieses Berichts bestehen darin, dass die Analyse auf einer explorativen Handsuche basiert, sich auf deutsch- und englischsprachige Leitlinien beschränkt und die tatsächliche Anwendung der Prinzipien in der Praxis nicht überprüft wurde.

Schlussfolgerung

Die Analyse internationaler Leitlinien zeigt einen methodischen Gestaltungsspielraum für Österreich. Die Wahl der Perspektive und die Art der relevanten Kosten sind dabei die zentrale Entscheidung mit politischem Charakter. Der Bericht liefert ein Gerüst für eine zukünftige österreichische Kostenerfassungsprozesse, welche in eine gesundheitsökonomische Leitlinie eingebettet werden können. Nächste Schritte sind die Analyse österreichischer Kostendatenquellen (LKF-System, Erstattungskodex, DHE-Datenbank etc.) und die Konzeptualisierung einer österreichischen Referenzmethode im Zuge eines Leitlinienentwicklungsprozesses.

1 Background

1.1 Introduction

Kostenerfassung in der Gesundheitsökonomie: Identifikation – Messung – Bewertung von Ressourcen

Cost data play a key role in health economic analyses (HEA) in assessing whether a healthcare intervention is efficient, socially "worthwhile" or affordable from a budgetary perspective. To obtain valid cost estimates, HEA relies on the fundamental practice of costing – the process of identification, measurement, and valuation of resources associated with healthcare interventions and policies. This involves 1) defining the analytical perspective, an adequate time horizon, and identification of necessary resources affected by the implementation of the intervention, 2) measurement of these resources – from direct medical costs like hospital stays, medications, to indirect and intangible costs (measurement) – and 3) assigning a monetary value to each unit of resource use.

Grundlage für Effizienzüberlegungen & Gesundheitsplanung

gesundheitsökonomische Leitlinien (z. B. UK, NL) definieren Referenzmethoden mit methodischen Vorgaben

A few healthcare systems, such as the United Kingdom (UK) [1] and the Netherlands (NL) [2], provide national health economic evaluation guidelines (HEEG), Health Technology Assessment (HTA) guidelines (HTAG), budget impact analysis (BIA) guidelines (BIAG) and costing manuals (CM) that establish a standardised reference case. This reference case defines the core methodological principles of the jurisdiction's HEA, including the analytical perspective, and best-practice instructions to costing, to ensure consistency and comparability across studies. These jurisdictions operationalise costing by providing standardised national cost collections. These collections contain unit costs, reference prices, or national tariffs for various resource units, e.g., hospital stay (per admission or per day), intensive care (daily rate), emergency department visits, clinic or primary care consultations (per visit), community nursing or therapy (hourly rate), diagnostic tests (per test), and medications (per tablet or vial) [3-5]. By combining resource use data with accurate unit costs, analysts can construct a transparent and methodologically robust total cost profile for each intervention.

Standardisierte Kostenkataloge liefern Einheitskosten (z. B. pro Krankenhaustag, Konsultation, Test)

sichert Vergleichbarkeit & Transparenz

österreichische Initiativen: DHE Unit Cost Online Database (seit 2016) & EU-Projekt PECUNIA liefern Referenzkosten & Kalkulationstools

In 2016, the Department of Health Economics (DHE) at the Medical University of Vienna developed a Microsoft Excel®-based, publicly accessible catalogue of unit costs drawn from published Austrian economic evaluations and costing studies: the DHE Unit Cost Online Database [6, 7]. Furthermore, the PECUNIA Project (ProgrammE in Costing, resource use measurement and outcome valuation for Use in multi-sectoral National and International health economic evaluAtions), funded by the European Union (EU), provides a set of reference unit costs, including estimates for Austria, and a set of templates to calculate unit costs that are comparable across countries and sectors [8, 9]. The project also highlights some practical challenges in harmonised unit cost calculation [9, 10]. Although both the DHE Unit Cost Online Database and the PECUNIA project were well-received by Austrian and international scientific communities, there are still some shortcomings regarding the availability and in routine use within HTA.

trotz wissenschaftlicher Anerkennung: Defizite bei Verfügbarkeit & Routine-Nutzung im HTA

fehlender Konsens zu Referenzmethoden & Kostenerfassung in AT

The DHE database improves access to unit costs, while the PECUNIA costing tools support cross-country comparability by facilitating the identification, measurement, and valuation of resource use. However, a key challenge remains: the lack of consensus on a health economic reference case and standardised methods across all stages of costing. Valuation – applying unit costs, reference prices, or national tariffs – is just one component of a comprehensive costing process within a reference case. For results to be valid, each preceding step must

follow a rigorous methodology. In Austria, current costing practices lack standardisation across the entire process. This gap can be partly explained by the limited role of efficiency considerations in Austrian healthcare decision-making and the absence of a national health economic evaluation guideline and reference case [11, 12]. Consequently, standardisation is lacking from the initial identification of resources from the relevant perspective, through the measurement and sourcing of data (e.g., LKF points and hospital controlling data) to the final calculation and application of unit costs.

Überblick internationaler Referenzmethoden & Kostenerfassung als Grundlage für österreichische Leitlinie

Against this backdrop, this project aims to give an overview of international reference cases in HEA and the associated costing approaches, providing a key foundation for a future national HEEG. The primary focus lies on applications in HEA for Austrian decision-making processes, such as HTAs conducted in the Austrian Appraisal Board for selected, high-priced, and specialised medicinal products in the inpatient sector [13, 14].

1.2 Problem Statement, Project Objectives and Research Questions

Problem Statement and Rationale of the Report

Problemstellung: keine nationale gesundheitsökonomische Leitlinie & geringe Rolle von Effizienzüberlegungen

In Austria, HEE has so far played a minor role in reimbursement decisions, and a HEEG with a reference case including a costing process and approach has not yet been defined or discussed [15-17]. However, against this backdrop, it is crucial to have a standardised reference case including a costing process. Standardised and validated cost data reduce data variability – ensuring that any cost differences between interventions reflect actual resource use rather than differing valuations of the same resources. Reducing heterogeneity within the cost data allows consistent comparison within Austria but also across different studies, sectors, and healthcare systems [8].

Objectives

Projektziele:

The project's main aims are to…

- Outline basic concepts and methods in the costing context.
- Compare international best practices and instructions regarding the health economic reference case and all major steps in the costing process (identification, measurement, and valuation).
- Propose best practice strategies for a reference case with respect to costing as a key component for a future Austrian HEEG.

Grundkonzepte der Kostenerfassung; Vergleich internationaler Referenzmethoden & Kostenerfassungsprozessen; Best-Practice-Strategien für AT

Non-objectives

Nicht-Ziele: keine(n) universielle(n) Referenzmethode & Kostenerfassungsprozess für AT

The report does not provide a final reference case for an Austrian guideline nor a universal costing method or full unit cos database for Austria.

Research Questions

Forschungsfragen:

The following research questions (RQ) will be answered in the course of the report:

- RQ1: What are the foundations of costs and the costing process, and what quality criteria ensure the validity of cost data in health economic analyses?

Grundlagen Kostenerfassung & Qualitätskriterien für valide Kostendaten?

- RQ2: Based on a comparative analysis of international guidelines and reference cases, what are the specific methodologies and standards used for resource identification, measurement, and valuation?

Kostenerfassungsmethoden in internationalen Leitlinien?

- RQ3: How can these international best practices be adapted to inform the development of a standardised costing process and health economic reference case for the Austrian context?

internationale Best Practices für AT?

2 Methods

2.1 Change in Protocol

Protokolländerung: Ursprünglicher Fokus auf Unit Costs → systematische Analyse internationaler Referenzmethoden & Kostenerfassungsprozesse wurde prioritär

The project's initial scope centred around unit cost sources and approaches to estimate unit costs. However, during the narrative literature review, country selection, and the piloting of the data extraction, it became evident that a systematic analysis of health economic reference cases and the broader costing process outlined in international HEEGs, HTAGs, and CMs was essential to address a part of the initial research objectives with sufficient depth. Consequently, the project scope was refined to prioritise this comprehensive review of international costing methodologies, which constitutes a higher-ranking objective given the current status of health economic evaluations and guideline development in Austria. To maintain a focused and feasible analysis, the investigation of specific unit cost frameworks, Austrian data sources, and the application was formally postponed to a subsequent research report. The initial project protocol can be consulted with the following link: https://aihta.at/page/measures-to-improve-cost-data-use-for-health-economic-studies-and-decision-making-overview-of-existing-frameworks-and-status-quo-in-austria/en.

2.2 Report Structure and PICo Scheme

Berichtsstruktur & PICo

This report synthesises health economic evaluation guidelines (HEEG), HTA guidelines (HTAG), budget impact analysis guidelines (BIAG), costing manuals (CM) – collectively referred to as guidelines – and relevant HTA-agency documents across multiple countries, with a specific focus on the costing process. Our aim is to compare international reference cases and their methods for identification, measurement, and valuation of resources, and to derive transferable principles for future use.

3 Schritte:

The work proceeds in three steps:

- An overview of the conceptual foundations of costing and quality criteria for cost data (Chapter 3 Foundations of Costing and Quality Criteria). — konzeptionelle Basis & Qualitätskriterien
- A country and guideline overview and a structured analysis and narrative review of the costing process by domain (e.g., Healthcare services, pharmaceuticals, medical devices, hospital services etc.; see Table 2-7 for all costing domains) (Chapter 4 Country and Guideline Overview). — Übersicht der Länder & strukturierte Analyse des Kostenerfassungsprozesses
- Discussion and critical reflection of implications of the findings for a future Austrian reference case including a costing process (Chapter 5 Discussion). — kritische Reflexion der Ergebnisse & Implikationen

Problem, Interesse, Kontext

The following Problem, Interest, and Context (PICo) scheme [18] guided identification, selection, and synthesis to address the research questions.

Table 2-1: PICo scheme

Problem	In Austria, HEE has so far played a minor role in reimbursement decisions. There are shortcomings regarding the implementation of a nationwide HEEG. A standardised reference case including a costing approach has not yet been defined or discussed. In addition, current practices in Austria regarding unit cost lack standardisation in data sources (e.g., Austrian Diagnosis-Related Group (DRG) system and hospital controlling data) and have regional variations (e.g., differences in unit costs across federal states or sickness funds).
Interest	■ RQ1: Overview of basic costing concepts and quality criteria of cost data. ■ RQ2: Overview of health economic reference cases and costing approach in international guideline documents. ■ RQ3: Summary and critical reflection of the findings.
Context	International healthcare context with a focus on countries describing the costing process/approach within their guideline or a separate costing manual.
Language of the literature/ publications	English/German
Publication types	■ Health economic evaluation guidelines ■ Budget impact analysis guidelines ■ Health Technology Assessment guidelines ■ Costing manuals ■ Health economic guideline associated documents (e.g., unit costs lists).

DRG…Diagnosis-Related Groups, HEE…Health Economic Evaluation, HEEG…Health Economic Evaluation Guideline, PICo…Problem, Interest, Context, RQ…Research Question

2.3 Foundations of Costing and Quality Criteria of Cost Data

Forschungsfrage 1:

To answer research question 1, we give an overview of the foundation of costing and costs. This task comprised four steps:

Grundlagen

- Conceptual foundation: We define economic costs – in the sense of opportunity costs – and explain the difference to financial costs.

Kostenerfassungsprozess

- Costing process and unit costs: We introduce the steps of a typical costing process, describe unit costs, and briefly outline cost functions.

Qualitätskriterien abgeleitet aus 5 Frameworks (CHEERS, Drummond-Checklist, EUnetHTA Core Model, ISPOR BIA, Good Practice Modellierung)

- Quality criteria of cost data: We derive common quality criteria (e.g., accuracy, precision etc.) from five frameworks and checklists commonly used in health economics. The five publications are representative for the variety of approaches that are relevant in HEA, i.e. evaluation of HEA and its reporting (CHEERS checklist, BMJ Guidelines/"Drummond checklist"), HTA (EUnetHTA Core Model®), budget impact analysis (ISPOR Principles for Budget Impact Analysis I and II), and decision-analytic modelling (Good Practice Guidelines for Decision-Analytic Modelling). The quality criteria from these frameworks complement general statistical standards and evidence-based medicine (EbM) principles for estimates and estimators. We describe each criterion and explain its implications for cost data and the costing process. Furthermore, we give an overview on the placement of each criterion (e.g., accuracy, precision etc.) within five frameworks. Table 2-2 lists the publications that were included to derive the quality criteria.

Beschreibung & Implikationen für Kostenerfassungsprozess

- Mapping criteria to the costing process: we map the quality criteria to the relevant stage(s) of the costing process to highlight when and where each criterion must be satisfied.

Zuordnung der Kriterien zu den Phasen des Kostenerfassungsprozesses

Table 2-2: Overview of publications outlining quality criteria of cost data

Publication by	Publication name	Aspect
Husereau et al. [2022] [19]	■ Consolidated Health Economic Evaluation Reporting Standards 2022 (CHEERS 2022) Statement: Updated Reporting Guidance for Health Economic Evaluations.	Reporting quality in health economic evaluations
EUnetHTA Joint Action 2 [2016] [20]	■ HTA Core Model® Version 3.0.	Health Technology Assessment guidelines/framework
Drummond and Jefferson [1996] [21]	■ Guidelines for Authors and Peer Reviewers of Economic Submissions to the BMJ.	Methodical quality of health economic evaluations[1]
Mauskopf et al. [2007] [23] and Sullivan et al. [2014] [24]	■ Principles of Good Practice for Budget Impact Analysis: Report of the ISPOR Task Force on Good Research Practices--Budget Impact Analysis. ■ Budget Impact Analysis-Principles of Good Practice: Report of the ISPOR 2012 Budget Impact Analysis Good Practice II Task Force.	Good practice for budget impact analysis
Philips et al. [2006] [25]	■ Good Practice Guidelines for Decision-Analytic Modelling in Health Technology Assessment: A Review and Consolidation of Quality Assessment.	Good practice for decision-analytic modelling

2.4 Overview of Reference Cases and Costing Processes in Identified Countries

To answer research question 2, we give a guideline overview and a structured analysis of the costing process. This task comprised four steps:

Forschungsfrage 2

- Identification of potentially relevant countries and guidelines (see Section 2.4.1).

Identifikation relevanter Länder & Leitlinien

- Selection of eligible countries and guidelines (see Section 2.4.2).

Selektion geeigneter Länder & Leitlinien

- Data extraction of relevant information regarding the reference case and costing process (see Section 2.4.3).

Datenextraktion zu Referenzmethode & Kostenerfassungsprozess

- Overview and analysis of the extracted information regarding the reference case and costing process (see Section 2.4.4).

Übersicht & Analyse der extrahierten Daten

[1] The Consensus on Health Economic Criteria (CHEC) checklist [22] is another checklist that serves the purpose to critically appraise the methodological rigor and internal validity of health economic studies. The BMJ checklist by Drummond and Jefferson [21] is the "ancestor" of the CHEC checklist. The CHEC checklist is a more extended version for systematic review appraisal but contains similar core principles for appraising methodological soundness.

2.4.1 Country and Guideline Identification

Länderidentifikation: ISPOR-Leitlinienübersicht

The starting point for identifying countries with relevant guidelines were the International Society for Pharmacoeconomics and Outcomes Research (ISPOR) guideline overview [26] (offline since the end of August 2025).

3 Übersichtsarbeiten zu internationalen Leitlinien zur Vervollständigung der identifizierten Leitlinien

Furthermore, we used the three reviews of international health economic evaluation guidelines, which were identified during the project scoping phase, with the latest review dating back to 2021, to validate and complete the identified guidelines of the previous step:

Table 2-3: Reviews of international health economic evaluation guidelines

Publication by	Year	Publication title
Zhao et al. [2018] [27]	2018	A Systematic Review of Pharmacoeconomic Guidelines
Sharma et al. [2021] [28]	2021	National Healthcare Economic Evaluation Guidelines: A Cross-Country Comparison
Daccache et al. [2021] [29]	2021	Economic Evaluation Guidelines in Low- and Middle-Income Countries: A Systematic Review

Erfassung relevanter Länder & aktuellsten Leitlinien aus

As a next step, all countries with guidelines and the most recent guidelines from the original source were documented in a separate file, and the following data were extracted:

Extrahierte Daten: Land, Leitlinientyp, Publikationsjahr, Sprache, Autor:innenzugehörigkeit

- Country
- Type of guideline (HEEG, HTAG, BIAG, CM)
- Year of publication
- Language
- Affiliation of authors

Abgleich mit GEAR & Handsuche

The final steps of the identification phase involved the validation against the Guide to Economic Analysis and Research guideline comparison (GEAR) [30] and a subsequent hand search confirming that all included guidelines were the most current versions available. The separate file with all identified countries and guideline documents is available in the separate Appendix.

2.4.2 Country and Guideline Selection

Screening auf Infos bezüglich Kostenerfassung, Costing Manuals & Unit Costs.

In the selection step, all identified guidelines were screened for detailed information on costing, costing approaches, costing manuals, and unit costs. The following search terms were used to identify relevant documents:

Table 2-4: Search terms for identifying information on costing in country guidelines

Search terms
The identified guidelines in English or German were searched for relevant information on costing using the following search terms: ■ Costing ■ Costing manual ■ Measurement ■ Valuation ■ Unit cost ■ Reference price

Countries satisfying at least one of the following guideline aspects were included:

- Countries with guidelines that include separate sections on costing.
- Countries with separate costing manuals.
- Countries with guidelines that include systematic information on the identification, measurement, and valuation of healthcare services or resources.

Einschlusskriterien: Leitlinien mit Abschnitten zur Kostenerfassung, Costing Manuals, systematische Infos zu Identifikation, Messung & Bewertung von Ressourcen

Table 2-5 gives an overview of the 12 included countries that fulfilled at least one of the criteria:

Table 2-5: Overview of included countries and guidelines

Country	Abbr.	Number of documents	Guidance issuing body ("HTA agency/body")	Document type(s)*
Australia [31, 32]	AUS	2	Pharmaceutical Benefits Advisory Committee (PBAC)	HTAG + CM
Belgium [33, 34]	BEL	2	Belgian Health Care Knowledge Centre (KCE)	HEEG incl. BIAG + CM (Hospital)
Canada [35-37]	CAN	3	Canadian Agency for Drugs and Technologies in Health (CADTH)	HEEG + BIAG + CM
Denmark [38-41]	DNK	4	Danish Medicines Council (DMC)	HEEG + CM
England & Wales [42]	E&W	1	National Institute for Health and Care Excellence (NICE)	HTAG
France [43]	FRA	1	French National Authority for Health (HAS)	HEEG
Germany [44]	GER	1	Institut für Qualität und Wirtschaftlichkeit im Gesundheitswesen (IQWiG)	HTAG
New Zealand [45, 46]	NZL	2	Pharmaceutical Management Agency (PHARMAC)	HEEG incl. BIAG + CM
Norway [47]	NOR	1	Norwegian Medical Products Agency (NoMA)	HTAG
Scotland [48]	SCT	1	Scottish Medicines Consortium (SMC)	HTAG
Netherlands [49, 50]	NDL	2	Zorginstituut Nederland (ZIN)	HEEG + CM
USA [51, 52]	USA	2	Institute for Clinical and Economic Review (ICER)	HEEG + BIAG

Abbr…Abbreviation, BIAG…Budget Impact Analysis Guideline, CM…Costing Manual, HEEG…Health Economic Evaluation Guideline, HTAG…Health Technology Assessment Guideline

** The documents are classified according to the following categories: HEEG (Health Economic Evaluation Guideline), HEEG+BIA (Health Economic Evaluation Guideline including Budget Impact Analysis, either integrated into the HEEG or provided as a separate document), HTAG (Health Technology Assessment Guideline), and Costing Manuals (CM), which outline the use of resource items.*

A total of 72 guidelines and costing manuals from 59 countries were available for the literature selection. The literature was screened by one researcher (CS). Most of the included documents are dedicated HEEG (9 documents from 7 countries), often accompanied by separate (2 countries) or integrated guidance for BIA (2 countries) and separate or integrated CM (6 CM documents from 6 countries). Five of the countries provide an HTAG, which integrates economic evaluation as a core component within a wider assessment of clinical effectiveness, safety, organisational and budget impact. The selection process is shown in *Figure 2-1*.

72 Leitlinien & Costing Manuals aus 59 Ländern gescreent

Eingeschlossene Dokumente: HEEG (9), BIAG (2), CM (6), HTAG (5)

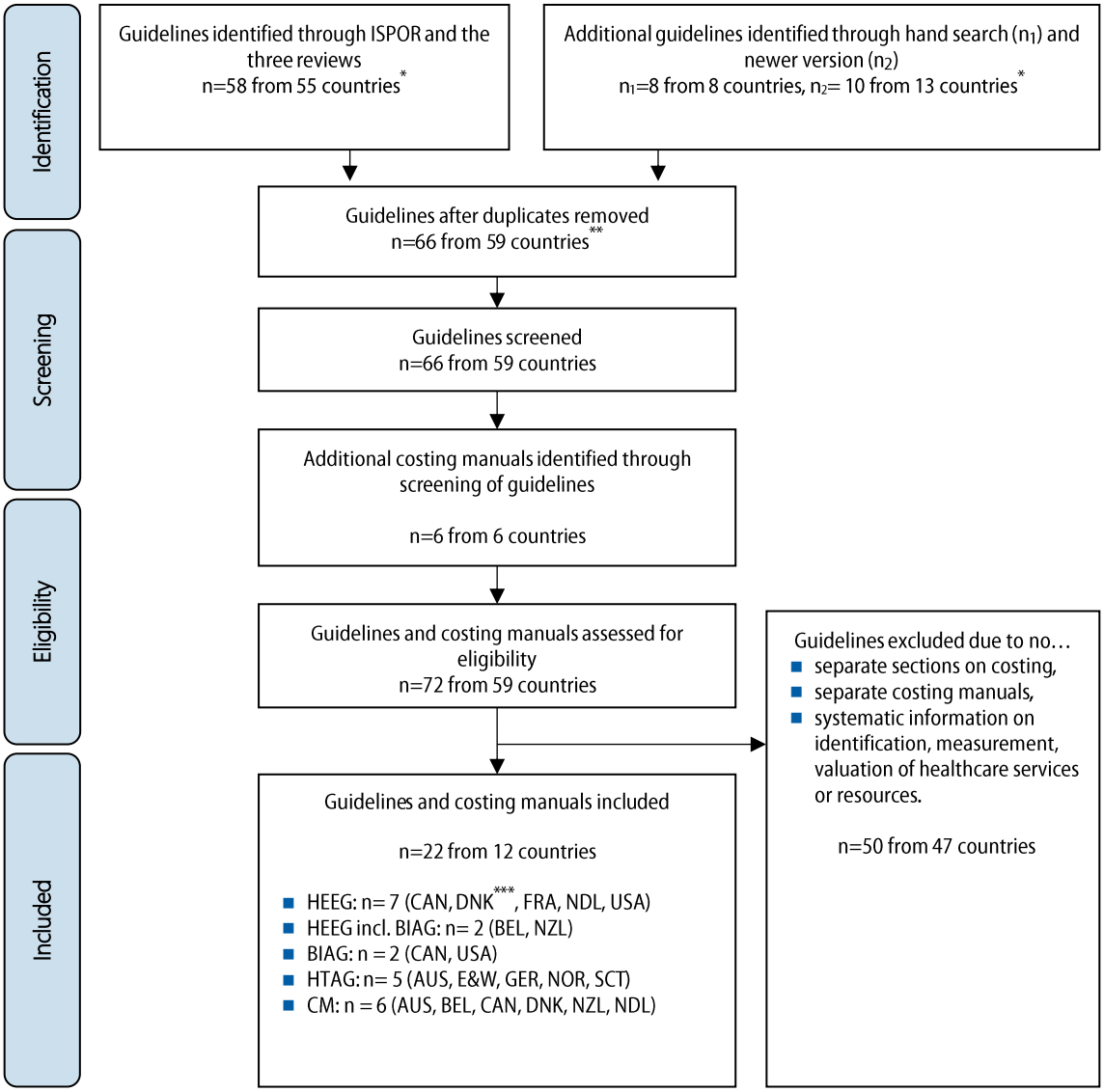

Figure 2-1: Selection process of the guidelines (PRISMA Flow Diagramme)

* *Mercosur (Argentina, Brazil, Paraguay, Uruguay) and the Baltic countries (Latvia, Lithuania, Estonia) have one guideline. Spain has three guidelines (National guideline, hospital guideline, Catalonia)*
** *In this step, an additional guideline for Estonia was identified.*
*** *Denmark provides multiple documents related to the health economic guideline including a legal text*

AUS…Australia, BEL…Belgium, BIAG…Budget impact analysis guideline, CA…Cost-analysis, CAN…Canada, CM…Costing manual, DKN…Denmark, E&W…England & Wales, FRA…France, GER…Germany, HEEG…Health economic evaluation guideline, HTAG…Health technology assessment guideline, ISPOR…Professional Society for Health Economics and Outcomes Research/International Society for Pharmacoeconomics and Outcomes Research, NDL…the Netherlands, NOR…Norway, NZL…New Zealand, SCT…Scotland, USA…United States of America

2.4.3 Data Extraction

Datenextraktion mit Fokus auf (i) kostenrelevante Elemente in der Referenzmethode &....

We carried out two separate extraction phases. In the first one, we extracted data on the guideline's reference case[2], focusing on elements that affect the costing process and the resulting costs in a potential HEE or BIA. To fulfil this task, we pre-specified extraction categories outlined in Table 2-6 and extracted information relevant to these categories. The pre-specified extraction categories are based on the systematic overviews listed in Table 2-3 and the evaluation criteria from the five frameworks and checklists listed in Table 2-2.

Table 2-6: Extraction categories for information on the guideline's reference case

Extraction categories of the guideline's reference cases	
■ Document type ■ Stringency/General guideline or submission only ■ Perspective ■ Focus (Pharmaceuticals, medical devices, all types of health technologies) ■ Analysis type (CUA, CEA, etc.) ■ Data sources (Clinical effect) ■ Other data sources (esp. for modelling) ■ Costs included (reference case)	■ Handling of non-reference case costs excluded in reference case (e.g., non-health care, indirect costs, intangible costs) ■ Modelling (Included: Yes/No, purpose and reasons) ■ Time horizon ■ Discount rates (Reference case) ■ Sensitivity/Uncertainty analysis* (Analysis type, discount rates etc.) ■ Budget impact (Time horizon, target population calculation, discounting etc.)

CEA…Cost-effectiveness analysis, CUA…Cost-utility analysis

**Mainly parameters affecting the cost or resource use component were extracted.*

...auf den (ii) Kostenerfassungsprozess

Gliederung nach 3 Phasen der Kostenerfassung:

In the second extraction phase, we extracted specific data on the costing process. To fulfil this task, we also specified extraction categories in advance to obtain information aligned with our project objectives. The majority of the extraction categories are based on fundamental knowledge in the health economic literature such as Drummond et al. [2015] and costing [54], and the evaluation criteria from the five frameworks and checklists listed in Table 2-2. The categories pertain to the costing approach and the three main costing phases:

- Identification of resources — Identifikation
- Resource use measurement — Messung
- Valuation of resources and costing domains (Healthcare services, pharmaceuticals, medical devices, hospital services etc.) — Bewertung

[2] A reference case in the health economic guideline context specifies the core methodological principles of the jurisdiction's HEA, including the analytical perspective, time horizon, discounting rate and best-practice instructions to costing, to ensure consistency and comparability across studies.

The pre-specification of extraction categories was complemented by the definition of new extraction categories we deemed informative for answering our research questions. This measure was essential to cluster the heterogeneous structure and reporting of the identified country guidelines. Furthermore, country- and system-specific characteristics that could not be synthesised into broader, cross-country categories could be highlighted. Table 2-7 provides an overview of the extraction categories relevant to the costing process, and an explanation of the methodological rationale for each category.

vordefinierte Extraktionskategorien durch neue ergänzt → ermöglicht Darstellung länderspezifischer Besonderheiten

Table 2-7: Extraction categories for the costing process

Extraction categories of the costing process	Definitions and explanations (Methodological rationale)
Costing Process Step I: Costing Approaches and Identification of Resources	
Costing Approaches (pre-specified)	Four different costing approaches exist: Top-down micro-costing, Top-down macro-costing, bottom-up micro-costing, bottom-up macro-costing. Costing approaches are not exclusionary and can be combined. The costing approach informs the entire costing process – all three stages – and is not limited solely to the step of resource valuation.
Identification of Resources and Costs (pre-specified)	Identification means determining what resources are consumed or targeted for costing (e.g., direct healthcare costs, direct non-healthcare costs, indirect costs, intangible costs, future costs) from a specific perspective. This category was informed by extracted data of the reference case outlined in Table 2-6.
Costing Process Step II: Resource Use Measurement	
Cost Units (pre-specified)	A cost unit is the specific, quantifiable unit of a healthcare resource to which a monetary value is assigned. It is the fundamental building block for costing, representing a single instance of consumption or provision, such as cost "per tablet", "per hospital day", or "per outpatient visit". The report provides complete cost units for the four primary domains (Non-Inpatient Healthcare Services, Pharmaceuticals, Medical Devices, and Hospital Services). However, for other domains such as productivity and residential care, the absence of a listed unit indicates a gap in the available data, not that these domains are omitted from formal costing guidelines.
Data Sources (pre-specified)	The Data sources domain serves to identify the origin of resources and provide also partial information on their valuation. Data sources can include clinical studies, administrative databases, protocols, published fees, or even expert input. Note that sources for resource use and pricing data are frequently intertwined and not fully disentangled. The specific methodologies and sources for valuation are elaborated in the Section 4.5.1 General Principles of Resource Valuation and are further detailed within each costing domain (e.g., "Healthcare services", "Hospital services").
Costing Process Step III: Valuation of Resources and Costing Domains	
General Principles of Resource Valuation (pre-specified)	The general principles of resource valuation give universal information on aspects that apply to all resource and costing domains. Information can include general sources for valuation, adjustment of international cost estimates, inflation adjustment etc.
Non-Inpatient Healthcare Services (pre-specified)	The "Non-Inpatient Healthcare Services" domain primarily covers general outpatient services, such as physician services (e.g., family doctors, specialists), and outpatient diagnostics or investigational services, such as imaging procedures, laboratory and pathology tests. Non-physician services are included also under this domain unless addressing specialised domains (e.g., residential care, home nursing, transport) requiring a distinct valuation with more scrutiny compared to standard healthcare services. Hospital outpatient services are also covered within this costing domain as a majority of included countries make an explicit distinction between costing of outpatient and inpatient hospital care by costing hospital outpatient care similar to non-inpatient healthcare services.
Pharmaceuticals (pre-specified)	The costing domain "Pharmaceuticals" addresses mainly the acquisition costs of the intervention and comparators of interest in HEE. If explicitly reported in guidelines, pharmaceutical dispensing and administration costs are included in the "Pharmaceuticals" domain; otherwise, they may be (already) included in the valuation of "Healthcare or Hospital Services" costs.

Medical Devices (pre-specified)	The costing domain "Medical Devices" addresses mainly the acquisition costs of the intervention and comparators of interest in HEE but may also include drug (delivery) devices including insulin pens, nebuliser units, syringes, and blood glucose indicator tests. Some guidelines indicate that the valuation of interventional device costing is included in the Healthcare services costing domain. Hospital-based (inpatient) costing of devices and diagnostic/investigational services are usually covered by the costing domain "Hospital services".
Hospital Services (Inpatient) (pre-specified)	The "Hospital Services" costing domain includes mainly valuation of inpatient services and acute care as these services are often valued based on bundled units (cost per case, cost per hospital overnight stay). Valuation of hospital outpatient services is mainly included in the "Non-Inpatient Healthcare Services". Denmark, France, and the Netherlands are the only countries that address costing of hospital outpatient services within the bundled, DRG-based costing approach of inpatient services.
Residential Care, Home Nursing, and Home Care	Care, especially long-term care, is often not uniformly funded by the formal healthcare system or does not fall into the healthcare sector and therefore the costing and specifically valuation has different aspects compared to "standard" healthcare or hospital services.
Transport, Travel Expenses, and Ambulance	Travel expenses (e.g., fuel, public transport fares) are mostly not payments for healthcare services or resources consumed within the healthcare system, but rather ancillary expenses incurred by patients to access care. These costs mostly occur outside the formal healthcare system (e.g., payment to transport providers rather than hospitals), aligning with the definition of direct non-healthcare costs in standard frameworks like the ISPOR Good Practices for Outcomes Research and WHO guidelines [55]. Ambulance services are typically classified as "Healthcare services" or "Hospital services". However, due to an overlap with general transport costs, they are subsumed under the costing domain "Transport, Travel Expenses, and Ambulance".
Productivity Costs, Patient and Caregiver Time, and Informal Care (pre-specified)	Productivity costs capture the cost of lost output in the formal labour market due to absenteeism or presenteeism. The valuation of patient and caregiver time is a key differentiator between guidelines that adopt a narrow healthcare system perspective and those that incorporate a broader societal or patient-inclusive viewpoint. Patient and caregiver time addresses mainly travel time due to treatment or illness regardless of where that time comes from (work, leisure, sleep). However, caution is advised for potential double-counting when travel for treatment occurs during work hours. Note that not all travel time equates to lost work time. Informal care is the unpaid care provided to someone with support needs by family, friends, or neighbours. Informal care is subsumed under patient and caregiver time.
Other Healthcare System-Specific Services	The information on valuation of other healthcare system-specific services are characteristics that could be assigned to previous costing domains but are presented separately as the valuation of these services gives healthcare system-specific insights.
Cross-Sectoral Aspects, Transfer Payments and Intangible Costs (prespecified)	This costing domain provides information on valuation of non-healthcare sector (cross-sectoral) costs, transfer payments, and intangible costs, such as costs to the educational sector due to the illness or costs resulting from pain.
Lump-sum Payments and Overhead Costs	Lump-sum payments are fixed reimbursements for defined services and may indirectly include overhead allocations, but they are not classified as overhead costs per se. E.g., for bundled services: If a lump-sum (e.g., per hospital stay) implicitly covers shared infrastructure, overheads may be allocated within it – but this is not their primary purpose. For pragmatic reasons, the valuation of both were summarised in one category.

Extraktionsprozess: Pilottest an 4 Ländern

Before one author extracted the data of all 12 countries, we piloted the extraction of four countries (Australia, Belgium, Canada, Denmark). After the extraction of the data by one author (CS), the second author (JE) checked the extracted data for consistency across all extraction categories. Inconsistencies and ambiguities were resolved and adapted.

Appendix

The separate file with all extraction categories and extracted data is available in a separate Appendix.

2.4.4 Country and Guideline Overview and Analysis

narrative Aufbereitung der extrahierten Leitlinien-Daten

We summarised and analysed the extracted information on the countries and guidelines. Most of the extracted data was narratively processed according to the structure in Table 2-7, with selected items tabulated. We proceeded as follows:

Dokumententyp, Anwendungsbereich, regulatorischer Status

- General overview: We provided a general country-level overview and key characteristics of the identified guidelines, including document type, scope, the stringency and regulatory status of the guideline (Section 4.1 General Overview of Countries and Identified Documents).

Costing-Ansatz, Perspektive, Datenquellen, Modellierung, Zeithorizont & Unsicherheit

- Costing-specific aspects: We descriptively analysed the analytical approach, perspective, data sources, modelling aspects, time horizon, and the handling of uncertainty. Furthermore, we described costing-specific aspects regarding the BIA. The focus of the descriptive analysis was on the specifications of the health economic reference case (Section 4.2 Costing-Specific Aspects in Identified Documents).

Darstellung von Gemeinsamkeiten & länderspezifischen Besonderheiten

- Costing process by country: We described each fundamental step of the costing process for each country, outlining commonalities based on the extracted, clustered data and highlighting system-specific characteristics:
  - Section 4.3: Costing approach and cost categories included in the reference case.
  - Section4.4: Recommended methods for the quantification of resources needed to provide the healthcare intervention.
  - Section 4.5: Valuation approaches by resource or costing domain (“Healthcare services”, “Pharmaceuticals”, Medical devices”, “Hospital services” etc.)

2.5 Quality Assurance of the Report

Qualitätssicherung: Internes Review & externes Review

As part of quality assurance, the report was reviewed by an internal reviewer (IZK) and one external reviewer (SM). The external reviewer was primarily asked to assess the following quality criteria:

- Technical correctness: Is the report technically correct (evidence and information used)?
- Does the report consider the latest findings in the research area?
- Adequacy and transparency of method: Is the method chosen adequate for addressing the research question, and are the methods applied transparently?
- Logical structure and consistency of the report: Is the report’s structure consistent and comprehensible?
- Formal features: Does the report fulfil formal criteria of scientific writing (e.g. correct citations)?

The AIHTA considers external peer review by scientific experts from different disciplines to be a quality assurance method of scientific work. The responsibility for the report content lies with the AIHTA.

3 Foundations of Costing and Quality Criteria

3.1 Economic Cost and Costing[3]

3.1.1 Definitions and Distinctions

Opportunitätskosten (Ressourcenverbrauch in alternativer Nutzung) vs. Finanzkosten (tatsächliche Geldausgaben)

In economic analyses, costs can be distinguished in two fundamentally distinct ways: Economic costs – also called opportunity costs – and financial costs. Economic costs (i.e., the use of labour and other resources in their next best alternative use) should not be confused with financial costs (i.e., actual monetary expenditures).

Turner et al. [2023] offer the following definition of opportunity cost:

> *"By pursuing one action, the potential benefit that could have been gained from the* ***next-best alternative*** *action is sacrificed – which is known as opportunity costs. […] or […] more formally, the opportunity cost of making a particular choice is the value of the next-best alternative that is foregone"* – Turner et al. [2023, p. 2]

…, or in short, opportunity cost is the …

> *"benefits forgone by particular use of resources"* – Palmer and Raftery [1999, p. 1551]

Opportunitätskosten umfasst auch Ressourcen ohne Geldtransaktion (z. B. informelle Pflege)

Transferzahlungen (z. B. Pflegegeld) sind keine Opportunitätskosten

When decision-makers in the healthcare system hire nurses, physicians, and other personnel or use other resources for a health-care-related need, these resources are no longer available for use elsewhere in the economy. This loss of production potential or "opportunities" elsewhere represents the "opportunity cost". Opportunity cost is the "price" of real resources that a decision or policy maker pays to keep the healthcare system running instead of using the resources for alternative purposes. Economic costs also include resources for which no financial transaction was made (e.g., informal care), or no market price exists. If a person is cared for by a relative, that person will probably receive care allowance, but this is not an economic cost in the sense of a market payment, but rather a transfer payment.

Gesundheitsopportunitätskosten: Nicht in Geld, sondern in Gesundheit selbst zu messen

Economic or opportunity cost are usually expressed in natural units or health-related quality of life (HRQoL) measures, such as healthy life years lost. Culyer [2015] also emphasises that …

> *"[…] the true opportunity cost of health care in a community, where the effectiveness of interventions is determined by their impact on health, is not to be measured in money – but in health itself."* – Culyer [2015, p. 13]

Monetarisierung nur aus Vergleichbarkeitsgründen

Economic costs are transferred in monetary currencies only for comparability reasons [58].

budgetäre Kosten können tatsächliche Kosten unterschätzen

Financial costs represent the actual monetary expenditures for a resource or cost unit (e.g., wages per hour, equipment prices, administrative expenses, cost per hospital stay) based on market prices or accounting records. Financial cost reflects "what was paid" rather than "what was sacrificed". For example, the unit cost of a physician consultation equals € 150 per visit, calculated from staff

[3] A major part of Section 3.1 is adopted and adapted from Strohmaier et al. [2025].

salaries, utilities, and depreciation of capital. Theoretically, in efficient markets[4] with fully used resource capacities, unit costs may correspond to opportunity costs (e.g., the unit cost of a visit in a fully booked magnetic resonance imaging department matches its opportunity cost). However, when resources are underused (e.g., empty hospital beds) financial costs understate true economic costs, as these capacities could be used for other purposes.

budgetäre Kosten für Budgetplanung

In practice, financial costs are typically used for budgetary planning such as budget impact analysis (BIA). In HEE, an opportunity cost approach is preferred. However, true opportunity costs, which are mainly relevant for HEE, can never be fully captured, as the underlying theoretical assumptions (efficient markets) are never completely fulfilled. Instead, either specific estimation methods are employed to approximate opportunity costs or unit costs serve as a pragmatic proxy for opportunity cost.

Opportunitätskosten in ges.ök. Evaluation.; aber nur Näherung möglich

Table 3-1 provides an overview of the differences between economic and financial costs based on the depiction by Turner et al. [2023].

Table 3-1: Difference in economic cost and financial costs based on Turner et al. [2023]

	Economic cost	Financial cost/Accounting cost
Description	Economic costs are relevant in analyses, which assess the efficiency of "competing" courses of action. The research question, context, perspective, and time frame impact economic costs. Especially, the study perspective (individual, healthcare system, etc) has substantial impacts on which costs and effects are included in the evaluation.	Financial costs represent the actual money or expenditures spent on resources, goods, and services and are used. The Ministry of Health or Social Security institutions use financial costs to plan the healthcare system. These costs are also relevant in budget impact analyses (BIA).
Costs included	All resources/resource costs relevant from the perspective taken (also costs for non-financial transactions).	Goods, services, inputs purchased and the time-dependent depreciated value of capital.
Valuation	Market prices are used as a proxy. In the absence of market prices, a "shadow price" reflecting the valuation of a good, service or intervention, is estimated.	Market prices/actual paid prices

3.2 Costs and Costing

3.2.1 Cost Units and Unit Cost

Kosteneinheiten gemeinsamer Nenner für Kostenerfassung

Unit costs, cost units, and total costs are interconnected concepts that together provide a framework to ensure comparability and accuracy of monetary expenses for healthcare services. Unit costs are typically expressed in cost units. Cost units reflect the basic "currency" for cost calculations and is the common denominator for cost measurement. Cost units in the healthcare setting typically include [5]:

[4] Allocative or market efficiency is a theoretical outcome within the assumptions of neoclassical economics. For allocative efficiency to be established, the assumption of perfect competition or perfect markets needs to be satisfied. This contains price taking behaviour by firms, no market entry or exit restrictions, no information asymmetries etc. However, perfect competition does not apply to real markets and is especially violated in the provision of health commodities and services [59].

- Per test (e.g., diagnostic tests).
- Per blister pack, per dose, per tablet, or vial (e.g., medications).
- Per visit or per consultation (e.g., emergency department visits, clinic or primary care consultations).
- Per admission or per day/night stay (hospital stays).
- Per patient, per case or treatment, or per case-mix, e.g., based on diagnosis-related group (DRG) ("DRG-based")
- Daily rate (e.g., intensive care service)
- Hourly rate (e.g., community nursing services or therapy).

Beispiele: pro Test, Tablette, Konsultation, Krankenhaustag/Tag/Nacht, Patient:in/Fall, DRG-basiert, Tagessatz (Intensiv), Stundensatz.

Unit costs represent the monetary price, valuation, or expense of an cost unit, e.g. € per additional diagnostic test. Total costs (TC) are usually calculated by multiplying the quantity of resources or services used in a patient's care pathway or working unit, i.e. the resource use, by a standard unit cost[5] assigned to each resource or service type:

Gesamtkosten = Ressourcenverbrauch × Unit Cost (z. B. € pro Test)

Verknüpfung von Mengengerüst & Bewertung.

$$Total\ Costs = Unit\ Cost\ \times Quantity \quad (1)$$

One typical way to approximate standard unit cost is to take the average cost of an intervention, health care service, and general output[6] in the healthcare system [60]:

Unit Cost-Schätzung: Näherung über Durchschnittskosten einer Intervention oder Outputs im Gesundheitssystem.

$$Unit\ Cost = \frac{Total\ Costs}{Quantity} = Average\ Cost \quad (2)$$

However, this approximation breaks down when services are heterogeneous, e.g., in terms of different cost units, or scale-dependent. For example:

Limitationen von Durchschnittskosten: Problem bei heterogenen Leistungen (z. B. Vermischung einfacher & komplexer Fälle) oder Skaleneffekten (fixe Kosten verzerren Unit Costs).

- Average costs in a primary care centre of € 325 per patient consultation might mix simple check-up visits (€50 per visit) and multi-component, more complex cases (€ 600 per visit), masking variation (variability) in unit costs.
- Smaller hospitals with higher fixed costs per unit may have inflated average costs compared to larger hospitals, even if their costs to provide an additional service are similar.

Therefore, the understanding of cost functions and the underlying cost distribution are important when calculating unit costs.

[5] The terms references prices or references costs are usually also used to describe unit costs [50, 60].

[6] In the literature, the term unit cost is also sometimes used to for costs of inputs, such as unit cost per medication dose [60].

3.2.2 Excursion: Cost Functions[7]

Basics for Interpreting Average and Unit Costs

Verständnis von Kostenfunktionen essentiell

Some basic knowledge of microeconomic theory and cost functions is a prerequisite to understand the process of costing and for interpreting unit costs [61]. In the following section, output-based notation commonly used in microeconomic theory is applied[8].

Kostenfunktionen repräsentieren Produktionsfunktion & Technologie

Cost functions measure the costs of producing a given level of output at given input price or unit cost. They reflect the underlying production functions and technology, which specify how one or more production factors may be combined to deliver healthcare services and interventions [60].

Usually, total costs, $TC(y)$, of a specific output y comprise of output-dependent variable costs ($c_v(y)$) and output-independent fixed costs (F)[9]:

$$TC(y) = C_v(y) + F \tag{3}$$

Durchschnittskosten: Näherung für Unit Costs – berechnet als Gesamtkosten geteilt durch Output

As mentioned, unit costs are often approximated by deriving average costs, i.e. the total cost divided by the output. In mathematical terms, the average cost equation is:

$$AC(y) = \frac{C(y)}{y} = \frac{C_v(y)}{y} + \frac{F}{y} = AVC(y) + AFC\ (y) \tag{4}$$

with $AVC(y)$ being the average variable costs and $AFC(y)$ standing for the average fixed costs.

Short- and Long-Run Cost

kurze Frist: fixe Kosten (z. B. Ausstattung) – nicht alle Produktionsfaktoren anpassbar

Average cost functions can take different forms. Although in some cases costs may remain constant at all production levels, they may become non-linear when factors of production can be adjusted or when a health care intervention or service provision expands [60]. Therefore, economists distinguish between short-run cost and long-run cost functions, as it is assumed that in the short-run, not all factors of production can be adjusted. For example, a radiology department or laboratory requires specific equipment before it can begin providing services.

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[7] While this chapter refers to the standard neoclassical cost functions, a cornerstone of the neoclassical perfect competition model outlined in basic microeconomic textbooks like Varian [2014], its empirical validity is contested [59]. As argued by Shaikh [2016], empirical evidence often points to L-shaped instead of U-shaped cost curves, with the latter being a result of the theoretical assumptions of neoclassical production functions (e.g., Cobb-Douglas) rather than an empirical observation. L-shaped cost patterns are likely highly relevant to healthcare with its significant fixed investments in facilities, equipment, and specialised labor. In Shaikh's "real competition" perspective, competition is less about optimal output choice and more about strategic and innovative cost reduction and capacity utilisation. The neoclassical model is applied here as a simplifying first approximation to introduce cost concepts. However, its limitations suggest that policy or analysis based solely on its assumptions may be misleading, and a more institutional and classical approach might be required for a complete understanding of healthcare costs [59].

[8] Output-based notation: $C(y)$; Input-based notation: $C(L,K) = wL + rK$ with L and K being labour and capital; Hybrid or empirical cost analysis notation: $C(y,L,K)$.

[9] Quasi-fixed costs are also output-independent but only accrue if a positive output amount is produced [61].

These costs will be fixed in the short-run and do not depend on the number of treated patients.

Furthermore, fixed costs may be spread across more output or personnel in the short-run, causing average costs to decrease as production increases, resulting in a downward-sloping average cost function. Conversely, if fixed costs are distributed on a low number of outputs or patients, the average cost will be relatively high [61].

Fixkostendegression: fixe Kosten auf mehr Output senkt Durchschnittskosten

In the long run, the average cost function may also be downward-sloping because all inputs can be adjusted [61]. An example would be a general practitioner (GP) or a hospital working at capacity. The fixed factor in the short-run are treatment facilities (space), specialised labour, and (capital-intensive) technological equipment. To see more patients, the GP or hospital management can only adjust variable factors by working longer hours (labour expansion) or the increase in (patient) volume of work per unit of time (labour intensification). However, working constantly at (physical) capacity can lead to inefficiencies due to fatigue of the GP and personnel or permanent overcrowding. The average cost per patient may start to rise because the fixed factor (treatment premises) is a major constraint. If the GP or hospital management decides to expand, the long-run begins, and all factors become variable. Long-run adjustments may include:

lange Frist: alle Faktoren variabel – z. B. Kapazitätserweiterung (Räume, Ausstattung) & Personalaufstockung

kurze Frist: nur Intensivierung/Verlängerung möglich → Ineffizienz bei Dauerbelastung.

- Capital and technology adjustments: The GP may move to a new, larger premises with more consultation rooms or the hospital management decides to expand by building new treatment facilities including acquisition of new equipment. A customised patient management system for the hospital setting can also be expensive and therefore capital-intensive.

Kapital- und Technologieanpassung

- Labour: The GP hires salaried GPs and an additional practice nurse, and the hospital hires additional staff (hiring of specialised labour can also take longer).

Anpassung des Faktors Arbeit

The long-run average cost slopes downward after expansion because substantial fixed costs, like facilities and equipment, are spread over a much larger patient base. Simultaneously, operational efficiencies may be gained through the specialisation of staff and a more productive division of labour, e.g., one GP may focus on chronic disease, another on acute care. This makes the cost of serving each additional patient lower than the previous average, thereby pulling the overall average cost down. The definition of long run is context-dependent. The long run represents the period required to adjust the fixed factor in question – such as capital (e.g., hospital facilities) or labour (e.g., contract adjustments or workforce restructuring) [61].

Fixkostenverteilung auf größere Pat.basis + Spezialisierung & Arbeitsteilung senken Durchschnittskosten

Economies of Scale and Economies of Scope

Improved service organisation can increase efficiency, but beyond a certain scale, management complexity can raise average costs, as seen in large hospitals or national health programmes expanding into remote areas [60].

This relationship between scale and cost is returns to scale: constant returns keep unit costs stable, increasing returns lower them, and decreasing returns raise them. Average costs can therefore decline, stay constant, or increase with output [61].

Skalenerträge:
zunehmend → sinkende Ø-Kosten
konstant → stabile Ø-Kosten
abnehmend → steigende Ø-Kosten

Economies of scope occur when joint service delivery saves costs by sharing resources or creating synergies. However, these can reverse into diseconomies of scope if managerial complexity, such as in large hospitals with diverse services, outweighs the benefits.

Verbundvorteile: gemeinsame Leistungserbringung kann Kosten senken

Evidence for these economies in healthcare is scarce and inconsistent [60]. One report [62] cites a study finding an optimal hospital size of 275 beds [63], while another suggests hospitals with fewer than 200 or more than 600 beds face diseconomies of scale [64]. Evidence is often indirect, using indicators like higher surgery volumes leading to better outcomes rather than direct cost data [65, 66].

aber: oft schwache Evidenz (z. B. für Volumen-Outcome-Beziehung)

Marginal and Incremental Costs

Marginal and incremental costs are of particular relevance to HEE. They are used in marginal analysis, which compares the additional (marginal) benefits of an intervention to its additional costs to find the optimal level of healthcare spending. This ensures efficiency and opportunity cost are considered, unlike decisions based only on average costs, which can cause inefficient over- or underspending [11].

marginale Analyse: Vergleich zusätzlicher Kosten vs. Nutzen

zur Vermeidung ineffizienter Über- oder Unterversorgung (anders als reine Durchschnittskosten).

The marginal cost ($MC(y)$) measures the change in costs for a given output change at any given output level y:

$$MC(y) = \frac{\Delta C(y)}{\Delta y} = \frac{C(y + \Delta y) - C(y)}{\Delta y} \quad (5)$$

Marginal cost measures a rate of change, i.e. the change in costs divided by a change in output [61]. As average costs, marginal costs are not necessarily constant and can be influenced by economies of scale and economies of scope.

Marginal = Kostenänderung pro Outputeinheit

Incremental cost is a broader concept describing the cost difference between two or more interventions for a change in output. The incremental cost-effectiveness ratio is a key form, representing the additional cost per additional unit of health gain (e.g., a quality-adjusted life year [QALY]) when comparing interventions [11]:

Inkremental = Kostendifferenz zwischen Interventionen → Grundlage für ICER (Kosten pro zusätzlicher QALY).

$$ICER = \frac{C(y_2) - C(y_1)}{E(y_2) - E(y_1)} = \frac{\Delta C(y_1, y_2)}{\Delta E(y_1, y_2)} \quad (6)$$

$C(\cdots)$ is the cost function mapping the actual outputs in monetary costs for each intervention. $E(\cdots)$ maps the outputs in health effects measures. The effects can also be valued in money terms as part of a cost-benefit analysis. However, this is rarely done in the context of health economics.

Real-world decisions, such as expanding treatment coverage or deciding on reimbursement of a new medicine, typically involve incremental changes rather than binary (zero or one) choices [61]. The use of marginal analysis ensures that the next unit of expenditure is evaluated in terms of its additional costs and benefits, rather than focusing solely on total costs and benefits. For instance, expanding a programme should be based on the marginal cost per life saved, not the average.

reale Entscheidungen (Ausweitung, Erstattung) betreffen inkrementelle Kostenänderungen

Nevertheless, marginal and average costs are closely related. When average costs are decreasing, each additional unit produced must cost less than the current average, pulling the overall average down. Conversely, when average costs rise, each new unit must cost more than the average, pushing it upward. This occurs because marginal costs determine whether the average cost curve slopes downward or upward at any given point [61].

Marginalkosten bestimmen Verlauf der Durchschnittskostenkurve

While some services can be characterised by a single unit cost, many require more nuanced analysis. Point(-in-time) cost estimates often lack utility for planning, as average costs frequently fluctuate. Unit costs depend on input-output relationships defined by the production technology and vary by output level and service scope, both of which evolve over time [60]. Therefore, it is important for the understanding and calculation of unit costs to distinguish between short- and long-run costs, average and marginal/incremental costs, and consider economies of scale and economies of scope.

Unterscheidung zwischen kurz-/langfristig, Durchschnitts-/Marginalkosten sowie Skalen- & Verbundefekte essentiell

3.2.3 Costing: Identification, Measurement, and Valuation of Resources

Costing in the health economic context is the complete task of estimating the cost of health care interventions and services. Turner et al. [2023] describe the process of estimating economic and financial costs in three steps [11]:

3 Schritte der Kostenerfassung (Schätzung):

1. Identification: Determining the resources needed to implement the interventions of interest. Identification answers "what?" is consumed, the type or category of costs (direct healthcare costs, direct non-healthcare costs, indirect costs, intangible costs etc.), over which time horizon, and from which perspective, such as the payer perspective, healthcare provider perspective, healthcare system perspective, or societal perspective.

Identifikation (Was wird verbraucht?)

2. Measurement: Measuring the amount of the needed resources to provide the interventions. Resource use measurement answers "how much?" of the resources are used.

Messung/Quantifizierung: (Wie viel wird benötigt?)

3. Valuation: Valuing each necessary resource by placing a monetary amount on it using unit costs or prices, e.g., average costs, fees, tariffs, market prices etc. ("price labelling").

Bewertung: Was ist der Preis der Ressource?

The process of costing is fundamental to both micro-level unit cost calculations (determining the cost of a specific service) and meso-level or patient-level economic evaluations (aggregating those costs to compare treatments). The results of these analyses can subsequently be scaled to the macro-level for budget impact or national expenditure forecasts.

Kostenerfassung grundlegend für Mikro-Ebene (Unit Costs), Meso-Ebene (ges.ök. Evaluationen) & Makro-Ebene (Budget Impact

Identification of Resources: The Perspective

In HEE, the chosen perspective is an essential determinant of the analysis's scope and relevance [25, 67]. It defines the point of view from which costs (and benefits) are assessed, effectively answering the question: "Costs and consequences for whom?". The perspective shapes the costing process, and ultimately, the recommendations derived from it. The most common perspectives include [68, 69]…

Perspektive bestimmt Analyseumfang: Kosten & Konsequenzen für wen?

Perspektiven:

- the patient perspective focusing mainly on out-of-pocket expenses and personal time,

Pat.-Perspektive

- the healthcare payer perspective

Zahler:innenperspektive

- the formal healthcare system or provider perspective (e.g., social security or government-provided healthcare system),

formales Gesundheitswesen

- the healthcare sector perspective considering costs falling on insurers, patients, and government health budgets,

Gesundheitssektor bzw. -budget

- the broadest view, the societal perspective, which aims to incorporate all costs (and benefits) regardless of who incurs (or receives) them.

Gesellschaftsperspektive

A specific perspective, like that of a healthcare payer or a government (healthcare) perspective, may be more relevant for a particular stakeholder facing a specific budget constraint. From a scientific vantage point, the societal is often considered the gold standard because it seeks to capture the full impact of an intervention on society [67, 69].

Zahler:innenperspektive für Budgetfragen relevant

Gesellschaftsperspektive erfasst gesamten gesellschaftlichen Impact („wissenschaftlicher Goldstandard")

Consequently, the perspective directly dictates which costs are deemed relevant for inclusion; an analysis from a hospital perspective, for instance, would ignore a patient's transportation costs, while a societal perspective would strive to include them.

Identification of Resources: Cost Categories

How costs are classified is fundamental to ensuring the analysis is comprehensive, comparable, and relevant for decision-makers. Over time, two approaches have evolved to categorise the type of costs: a traditional, functionally-based system and a more refined and policy-relevant sectoral approach [19, 21, 53, 70].

Kostenklassifikation: traditionell-funktional vs. sektoral (policy-relevant)

The "Old" Classification System: A Functional Perspective

The traditional system, which has been the main approach of health economics for decades, categorises costs based on their functional relationship to the disease and the healthcare system [19, 21]. Its primary goal is to capture the impact of a disease or intervention by looking beyond the direct healthcare-related resource use. By including direct non-healthcare and indirect costs, it argues that the true cost of illness is much broader than what is reflected by healthcare expenditures. This makes it particularly useful for broad public health planning and understanding the full economic burden of a disease. This system is built on three main pillars [71]: Direct costs, indirect costs, and intangible costs. The functional classification system does implicitly account for cross-sectoral costs in a fragmented way, if a broader perspective is taken. Cross-sectoral costs such as costs incurred in the education, labour market, criminal justice, or social care sector are split between the direct non-healthcare cost category (for direct payments to other sectors) and indirect costs (for the broader economic impact on productivity) [72].

traditionelle Kostenklassifikation: erfasst Krankheitslast über direkte medizinische, direkte nicht-medizinische & indirekte Kosten

sektorübergreifende Kosten fragmentiert abgebildet (direkte nicht-med. oder indirekte Kosten)

Direct Costs

Direct costs: These are the tangible resources consumed for the prevention, diagnosis, treatment, and rehabilitation of a disease [54, 71]. They are further split into:

direkte Kosten

- Direct healthcare costs: Resources used within the formal healthcare sector. This includes costs like physician salaries or healthcare services in the outpatient setting, hospital inpatient services, pharmaceuticals, and medical devices.
- Direct non-healthcare costs: Resources including time incurred by the patient, caregivers, and family due to the illness but falling outside the formal healthcare system. These are often out-of-pocket (OOP), such as transportation to appointments or co-payments. Furthermore, time spent on treatment, care, and travel during leisure hours, weekends, or vacations instead of leisure activities are usually classified as direct non-healthcare costs. Cross-sectoral costs are also assigned to this category, if a broader perspective is taken.

medizinische: Innerhalb des Gesundheitssystems (Personal, Arzneimittel etc.)

micht-medizinische: außerhalb des Systems (Transport, Zuzahlungen, Zeitaufwand)

Indirect Costs

indirekte Kosten bzw. Produktivitätskosten: Wert des verlorenen „Marktoutputs" durch Morbidität (Absentismus, Präsentismus) & Mortalität

This category moves beyond simple resource use to capture costs not directly related to healthcare services. Indirect cost also includes the economic consequences of the disease, such as lost productivity [54]. Usually, it represents the value of lost market output due to morbidity (time away from work, so-called absenteeism or reduced productivity during paid work, so-called presenteeism, or reduced leisure time) and mortality (premature death) [73]. According to Turner et al. [2025], the term indirect cost is often confusing in health economics because it conflicts with its established meaning in business, where it denotes overhead or supporting activities. To avoid this ambiguity, there is a shift towards using the more precise term productivity cost. A broader interpretation of indirect cost could also encompass impacts on other sectors or long-term macroeconomic losses [54].

Ansätze:

Nevertheless, two approaches exist to value indirect or productivity costs [74]:

- The human capital approach (HCA) posits that society loses an individual's future production when they leave the workforce prematurely due to death or disability [75, 76]. The HCA values lost productivity as total forgone wages (assuming permanent loss). This forgone wages or lost production is typically estimated using average income data.

HCA: Verlust des gesamten zukünftigen Einkommens (dauerhafter Ausfall)

- The friction cost approach (FCA) limits costs to the temporary friction period until workforce replacement [76, 77], i.e. a long-absent employee will be replaced from the "internal" labour market or by an unemployed individual [75]. FCA may better reflect societal productivity loss in economies with unemployment [35], as it assumes vacant positions can be refilled within a set timeframe (friction period) to restore pre-absence productivity levels.

FCA: Begrenzt auf Reibungsverluste bis zur Wiederbesetzung – realistischer bei Arbeitslosigkeit.

There is no clear consensus[10] on the best instrument or approach to measure productivity impacts [74, 76-78].

Pat.-Zeit & informelle Pflege: Produktivitätskosten (Lohnausfall) oder direkte nicht-med. Kosten (Versorgungskosten)?

Furthermore, there is ongoing debate on how to classify patient and caregiver time as well as informal care: as a productivity cost (lost wages) or a direct non-medical cost (cost of care). This variation in classification underscores the need for consistent methodology [54]. The next subsection strives these ambiguities (Excursion: Ambiguities with Productivity Costs and Patient and Caregiver Time).

Intangible costs

intangible Kosten: nicht-monetäre Krankheitslast (Schmerz, Leid, Angst)

Intangible costs are the most difficult to measure and value. These costs represent the non-monetary aspects of disease, such as pain, grief, suffering, and anxiety [53]. While critically important to a patient's quality of life, they are rarely valued in monetary terms [79]. Instead, they are often captured within the outcome measure of an evaluation, for example, within the QALY through its quality-of-life weights [80].

[10] Some scholars favour the FCA over the HCA, as it yields lower estimates of productivity loss [53]. A review noted that FCA use is concentrated in countries like Canada, Germany, and the Netherlands, where it is officially endorsed [74]. This approach consistently results in smaller loss estimates than the HCA, but the difference varies widely. The authors highlight that without standardised methods, comparing productivity costs across studies remains challenging.

Excursion: Ambiguities with Productivity Costs and Patient and Caregiver Time

Exkurs: Überschneidung von Produktivitätskosten & Pat.-/Caregiver-Zeit (präzise Trennung essentiell)

A critical challenge in HEE with a societal perspective is the clear distinction between productivity costs and patient and caregiver time including travel time and informal care [54, 81]. A potential overlap exists because both concepts attempt to place an economic value on time [53]. The confusion often arises because productivity costs are a specific economic term, while patient and caregiver time is a category of resource use that can be valued in different ways. A precise distinction is essential to avoid double-counting and to provide transparent, actionable results for decision-makers.

Produktivitätskosten: verlorene Marktproduktion (relevant für Staat & Arbeitgeber)

- Productivity costs are typically a macroeconomic measure. They represent the value of lost market production due to health-related absenteeism, presenteeism, disability, or premature mortality [73-78]. These costs are in the primary interest of the government, employer or the broader economy. They want to know the impact on workforce participation and economic output.

Pat.-/Caregiver-Zeit: Opportunitätskosten der Zeit für Gesundheitsaktivitäten

- Patient and caregiver time (including travel and informal care) is a microeconomic measure of resource consumption and burden. It represents the opportunity cost of all time spent by patients and their informal caregivers on health-related activities, regardless of the source of that time (work, leisure, etc.) [54, 81]. The primary perspective is that of the individual or household.

Zeit außerhalb Arbeitsmarkt:

Not all patient and caregiver time is lost productivity. A large portion of this time falls outside the formal labour market but still embody opportunity costs. Patient and caregiver time includes:

Freizeitverlust

- Time spent on treatment, care, and travel during leisure hours, weekends, or vacations instead of leisure activities.

unbezahlte Tätigkeiten (informelle Pflege, Haushalt etc.)

- Time spent on unpaid activities (e.g., informal care, additional household tasks, childcare by relatives due to illness of the parent) that are not captured in the gross domestic product (GDP) but represent a real loss of welfare.

Zeit von Rentnern/ Arbeitslosen

- Time spent by retired individuals or the unemployed on upaid activities.

Doppelzählung oder Unterschätzung am Beispiel Reisezeit

Travel time is a perfect illustration of the overlap because a single journey can be viewed through two different lenses. A patient or accompanying caregiver who travels for two hours for a chemotherapy appointment can take time off work. Then the full two hours count as travel time, and the full two hours also count as a productivity cost. If they travel on a weekend, the full two hours count as travel time, but zero hours count as a productivity cost. Hence, the same two hours spent travelling to a clinic can be a component of patient and caregiver time (a direct non-healthcare cost) or a productivity cost if and only if it causes an absence from paid work. Failing to separate them leads to either double-counting or underestimation.

direkte nicht-med. Kosten werden zu Produktivitätskosten nur bei Verzicht auf bezahlte Arbeit

The same logical distinction that applies to travel costs also helps clarify the categorisation of informal care. Historically, informal care often operated and still operates outside formal healthcare structures and financing. Therefore, it often remained an unaccounted component of total healthcare provision [81]. However, in recent years, the increasing adoption of the societal perspective in research and health policy has driven a critical shift. This broader viewpoint has spurred a growing acknowledgment of the economic value of informal care [67]. Informal care is usually understood as a direct non-healthcare cost [54]. The direct resource input into patient care is equal to a nurse in home care. Informal care may only become a productivity cost if the caregiver specifically

sacrifices paid working hours to perform it. The informal caregiver is providing the exact same service, but without a formal monetary transaction.

Pat.-Zeit = Wohlfahrtsverlust (Freizeit, Familie)

Produktivitätskosten = Marktoutput-Verlust (Tauschwert)

However, another argument to explicitly distinguish between productivity cost and patient and caregiver time is that this amount of time measures the disutility (burden) and opportunity cost to the patient or caregiver. This time could have been spent on leisure, family, or other valued activities. Its valuation captures the full welfare loss. Productivity cost measures the loss of market-valued goods and services (exchange value) to the wider economy. It is an output metric, not a full welfare metric. By making a qualitative distinction, one acknowledges that an hour lost from leisure is different from an hour lost from work, even if the same monetary value is assigned, or the same valuation method is applied for simplicity.

perspektivenabhängig:

Gesellschaft: Beides relevant – keine Doppelzählung

Zahler: nicht relevant (Ausnahme: Krankenstandsgeld)

Pat: Beides reale Opportunitätskosten (Zeit & Einkommen)

In summary, time can be a direct non-healthcare cost and may also be interpreted as an indirect cost (productivity cost). From a societal perspective (the gold standard in economic evaluation), both direct non-healthcare costs (the time itself) and the resulting indirect costs (lost productivity) should be considered, but not double-counted. From a healthcare payer perspective, e.g., a healthcare insurance institution or an insurance company, it depends. Normally, from a healthcare payer perspective in non-public healthcare systems neither is included, as the payer doesn't reimburse for travel time or lost wages. In some public healthcare systems, the healthcare payer partially compensates for the loss of income due to illness for a specific time (e.g., 26 weeks in Austria). The prerequisite is a medically certified sick note. From a patient perspective, both are very real (opportunity) costs [82]. The travel time is a direct personal burden, and the lost wages has a direct financial impact[11].

The "New" Classification System: A Sectoral (Societal) Perspective

sektorale Klassifikation: explizite, budgetrelevante Sektorentrennung, Produktivitätskosten separat, transparente Lastenverteilung

While comprehensive, the use of the "old" system faces practical challenges. The functional system puts emphasis on indirect costs. However, the estimation of indirect costs (productivity losses) may be often highly uncertain and could dominate an analysis, making a healthcare intervention look cost-effective. This could skew decisions away from interventions for populations not in the formal workforce, such as the elderly or children. A sectoral classification does not neglect productivity cost, but the emphasis is on an explicit sector distinction [8, 53, 83]. In many HEE with a sectoral distinction of costs, productivity cost is presented as a separate item alongside the relevant sectors. Furthermore, the sectoral classification system aims to be more transparent and directly informative about who bears the financial burden [53]. Therefore, the sectoral perspective can be viewed as more decision-maker or policy-friendly as it follows an accounting or budgeting approach.

Healthcare Sector Costs

Gesundheitssektor: entspricht weitgehend direkten med. Kosten

These costs are almost identical to the direct healthcare costs of the functional perspective but may also include healthcare related costs outside the formal healthcare insurance system. They represent the costs falling on any payer

[11] The valuation of patient and caregiver time and productivity costs are presented separately in the Section 4.5.8 on Productivity Costs, Patient and Caregiver Time, and Informal Care of this report to enhance interpretability. Included guidelines do not have a universal approach in valuing these cost domains. Patient and caregiver time cost is mostly interpreted as time spent on treatment valued using a state mileage allowance or the average wage to assign a consistent opportunity cost. Productivity costs are mostly time lost from paid work valued using the FCA or HCA.

within the healthcare sector, including insurers, government health programmes, and OOP payments for pharmaceuticals or medical services [54, 68].

Other Sector Costs

andere Sektoren: Soziales, Bildung, Arbeit, Justiz

This is a crucial addition for a full societal perspective. It captures costs that fall on sectors outside of health and the immediate patient or family. For example, social care services, educational systems (e.g., for a school-based vaccination program), employment or the criminal justice system [8, 83-85].

Patient and Family Costs

Pat.- & Familienkosten:

This category bundles costs incurred outside the formal healthcare system by patients and their families. It includes:

- OOP payments for healthcare: This is a transfer from the patient to the healthcare sector. Therefore, it may also be categorised in the healthcare sector directly. — OOP-Zahlungen
- Time costs of receiving care (travel and waiting time). — Zeitkosten & Produktivitätsverluste (wenn nicht separat)
- Productivity losses borne by the patient and family, if not separately categorised as productivity costs.
- Other non-healthcare sector costs like childcare or home modifications. — sonstige Kosten (z. B. Kinderbetreuung)

Productivity Costs (Societal Perspective)

Produktivitätskosten: verlorene Produktivität außerhalb Patient & Familie

Some guidelines or HEE retain this as a separate category to emphasise its importance. These are the costs of lost productivity outside the patient and family, typically falling on employers (through sick pay and temporary replacement) and society at large (through lost tax revenue and reduced economic output).

Identification of Resources: Connection Between Perspective and Cost Categories

Verbindung zwischen Perspektive & Kosten

Current health economics practice reveals no consensus on a superior cost categorisation system. While the "new" classification is trending in more recent literature [84], both the sectoral approach and the "traditional" system remain widely used in guidelines [44] and HEE. Also, the choice of perspective varies depending on the context and the question that a HEE aims to answer [68]. Each approach has advantages, disadvantages, and serves a different purpose.

Klassifikationsart ändert nicht den Kostenumfang, sondern Darstellung & Zuordnung

However, the connection between the analytical perspective and cost categories is fundamental, yet it is crucial to understand that the choice of categorisation system should not inherently alter the completeness of the considered cost. Rather, it affects the presentation of how those costs are reported and mapped to the chosen perspective. As mentioned, the functional approach groups costs by their economic function, while the sectoral approach reorganises the costs according to who bears the financial burden providing a more direct link to the decision-maker's budget. Therefore, the distinction between these two systems is rather artificial from a scientific viewpoint and is made mainly to serve accounting purposes of policy and decision-makers.

Übersicht Perspektive & Kostenkategorien

Table 3-2 integrates the analytical perspectives and both cost categorisation classifications, thereby acknowledging both the traditional and sectoral classification systems.

Table 3-2: Analytical perspective and cost categories adapted from Sittimart et al. [2024], own depiction

Cost category	Perspective				
	Patient (and caregiver)	Healthcare payer(s)	Healthcare provider	Healthcare sector	Societal
Direct healthcare costs	⊕*	✓	✓	✓	✓
Direct non-healthcare costs	✓	⊕*	X	✓	✓
Indirect costs (Productivity costs)	⊕	X	X	X	✓
Patient and caregiver time (travel time and informal care)	⊕	X	X	X	✓
Intangible costs	✓	X	X	X	✓
Other sector costs (Social care sector, education sector, criminal justice sector, employment etc.)	X	X	X	X	⊕**

✓…*Yes*

⊕…*Varies/Depends*

X…*No*

** In Bismarckian social security or Beveridge-type healthcare systems, a single patient pays partially and indirectly via social security contributions (Bismarckian) or taxes (Beveridge). The healthcare payer perspective usually covers costs incurred by a third-party, such as a social security institution, health insurer or government agency, for healthcare services. However, in Bismarckian or Beveridge systems the social security community or total potential patient community pays for healthcare.*

*** A limited societal perspective excludes spillover effects on non-healthcare sectors, while a full societal perspective includes them.*

Pat.-Perspektive: OOP, Reisekosten, Produktivitätsverluste (Lohnausfall), Zeitkosten (Reise, informelle Pflege)

From the narrow patient perspective, only costs borne by individuals and their potential caregivers (non-healthcare costs) are included, such as OOP payments, travel costs, and productivity losses. OOP payments and travel costs are usually classified as direct non-healthcare costs in the public healthcare context. Direct health-care costs are usually paid by the public healthcare system. However, in Bismarckian social security or Beveridge-type healthcare systems, a single patient pays partially and indirectly via social security contributions (Bismarckian) or taxes (Beveridge) to the public healthcare system. Therefore, direct healthcare costs may also be included from a patient perspective. Indirect costs may also be relevant from a patient or caregiver perspective if productivity losses in form of lost wages due to an illness or intervention arise. Time spent on travel time and informal care by the patient and caregiver also represent a real loss of welfare and may be relevant for a formal acknowledgment in HEEs from a patient perspective. As already mentioned, intangible costs are rarely valued in monetary terms [79]. However, they are relevant to a patient's quality of life and need to be acknowledged, at least on the outcome side [80].

The healthcare payer perspective is narrower still, focusing solely on the direct healthcare costs reimbursed by a specific payer [68]. However, the healthcare payer perspective usually covers costs for healthcare services incurred by a third-party, such as a social security institution, health insurer or government agency. In Bismarckian or Beveridge systems the social security community or total potential patient community contributes to the public healthcare system. Simultaneously, if the patient community is seen as the payer, OOP or co-payments need to be included.

Zahler:innenperspektive: Fokus auf erstattete direkte med. Kosten (Krankenkasse, Sozialversicherung, Staat)

The healthcare provider perspective includes all direct medical costs by its service providers or partners. In the case of a Bismarckian or Beveridge public healthcare system the healthcare provider and payer perspective can fall together.

Leistungserbringerperspektive ≈ Zahler:innenperspektive

The healthcare sector perspective expands the view to all direct medical costs, regardless of payer, and direct non-healthcare costs. This perspective excludes productivity losses.

Gesundheitssektor. direkte med. + direkte nicht med. Kosten

The societal perspective could be further distinguished in a comprehensive societal or global perspective and a limited societal perspective [68]. The societal perspective includes all relevant costs, regardless of sector. This includes direct medical costs, direct non-medical costs (like travel and informal care), indirect costs (productivity losses), and costs falling on other sectors such as criminal justice, employment, social care or education. It is the only perspective that captures the full economic burden in all societal-relevant sectors. Transfer payments are still excluded, because they are no consumption but only redistributive, financial flows. The limited societal perspective excludes spillover-effects to other sectors [68, 86].

Gesellschaftsperspektive umfasst Kosten weiterer Sektoren (Soziales, Justiz, Bildung etc.)

begrenzt gesellschaftliche Perspektive: keine intersektoralen Spillover-Effekte

A scientifically rigorous global perspective, in upholding the imperative to transcend the state, compels the inclusion of all costs, everywhere [68, 87]. It would incorporate all sectoral costs including transnational-spillovers irrespective of the national border in which they occur, ensuring the analysis is guided by the universalist principles of scientific inquiry rather than the normative constraints of the nation-state.

globale Perspektive: transnationale Spillover → überwindet nationale Grenzen (wissenschaftlich umfassend & universell)

Measurement and Valuation of Resources: Costing Approaches

In costing, methodologies are defined by two key axes: the direction of the calculation (top-down vs. bottom-up) and the level of detail in measuring resources (macro-costing vs. micro-costing) [88, 89]. The micro vs. macro distinction primarily refers to resource identification and measurement, answering the question, “How detailed is the list of resource ingredients?” In contrast, the top-down vs. bottom-up distinction primarily addresses valuation, answering the question, “How do we put a price or unit cost on these resource ingredients?” [54, 71]. Table 3-3 shows he costing approach matrix addressing resource use and valuation aspects.

Methoden der Kostenerfassung:

Mikro/Makro: Detailtiefe der Identifikation & Messung von Ressourcen („Was wird erfasst?“)

Top-down/Bottom-up: Richtung der Bewertung („Wie wird bepreist?“)

Table 3-3: Overview of different costing approaches adapted from Tan et al. [2009]

Resource identification and measurement

Accuracy →

Valuation Accuracy ↓

	Macro-costing (Aggregated resource use data)	Micro-costing (Detailed resource use data/specific resource lists)
Top-down (allocated or pre-set costs)	Top-down macro-costing ■ Resources (Macro): Uses total volume metrics on an aggregate level (e.g., total inpatient days in a hospital, total physician consultations of a single physician or healthcare region). ■ Valuation (Top-Down): Uses an allocated share of a total budget of a cost department or healthcare service bundle (e.g., hospital department, total costs for GP consultations), resulting in implied average costs per patient (e.g., € 5,000 per discharged patient).	Top-down micro-costing ■ Resources (Micro): Measures specific, actual resources used (e.g., staff time, medical device, pharmaceuticals etc.). ■ Valuation (Top-Down): Values resources with standardised (or average) unit costs (e.g., mostly from a national database or unit costs from costing studies).
Bottom-up (actual or specific costs)	Bottom-up macro-costing ■ Resources (Macro): Uses estimated resource amounts (e.g., estimated length of stay). ■ Valuation (Bottom-Up): Builds a total by applying actual, specific unit costs to the resource estimates (e.g., exact invoice price, exact salary).	Bottom-up micro-costing ■ Resources (Micro): Measures specific, actual resources used (e.g., staff time, medical device, pharmaceuticals etc.). ■ Valuation (Bottom-Up): Values resources with actual, specific unit costs (e.g., exact invoice price, exact salary).

Aggregierte Ressourcenerfassung (Makro) vs. detaillierte Einzelressourcenerfassung (Mikro)

Macro-costing involves identifying and measuring resources at an aggregate level, using broad categories such as the total number of inpatient days or physician consultations. In contrast, micro-costing uses a detailed list of every input consumed (inventory), such as specific staff time, supplies, and medications, to calculate a total [34, 88].

Top-down: aggregierte Daten (e.g., KH-Finanzbuchhaltung) vs. Bottom-up: Summe spezifischer Einzelkosten pro Leistung

Concurrently, a top-down approach to valuation uses centralised, aggregate data (e.g., from a hospital's financial administration or other data at department, hospital or national level) and allocates costs to specific services [71]. Usually, the aim of top-down costing is to estimate average costs. Conversely, a bottom-up approach values resources by analysing and summing the specific costs of personnel, equipment, and materials for each individual pharmaceutical, medical device, healthcare or hospital care service. Hence, the choice between top-down vs. bottom-up is driven by data availability and the components of the final healthcare service.

Top-down bei homogenen & Bottom-up bei heterogenen Leistungen

Top-down costing is suitable for homogeneous healthcare service with limited input components, e.g., only time spent for the service. In contrast, bottom-up costing is adequate for heterogeneous healthcare services for which specific cost data is available, as it calculates total cost by considering each service component or resources used (pharmaceuticals, medical device) for the final healthcare service individually [34].

These two spectrums combine to form four costing approaches. However, the chosen costing approach always implies a fundamental trade-off between feasibility, accuracy, and precision. The four primary approaches serve distinct aims, from high-level budgeting to precise reimbursement validation.

4 Kostenansätze → Trade-off zwischen Machbarkeit, Genauigkeit & Präzision.

Bottom-Up Micro-Costing

The goal of bottom-up micro-costing is to determine the precise cost of a specific patient's care ensuring high reliability [34, 71, 88], making it the "gold standard" among the costing approaches. Its philosophy is to capture cost truth by identifying, measuring, and valuing each specific resource used for an individual patient with actual quantities and actual unit costs. This could mean tracking the exact hours spent for a specific healthcare service and pairing it with the exact invoice price of a medical device such as an implant. This yields both high precision and high accuracy, resulting in a bottom-up cost calculation that reveals cost components that have a great impact on the total costs. However, this approach has intensive data needs (actual invoices, individual timesheets, and detailed medical records) and demands considerable researcher involvement.

Bottom-up Mikro-Costing: "Goldstandard" → präzise Kostenerfassung pro Pat.

Top-Down Micro-Costing

The central goal of top-down micro-costing is to calculate standardised costs for activities across the health system. Within the approach the specific resources consumed are identified, which ensures high precision, but values them using pre-defined, averaged (unit) costs from standardised unit costing approaches and national databases or unit costs from costing studies, which may have an impact on accuracy [88]. In DRG-based systems, it can be the primary method for setting national tariff prices or for calculating DRG-based unit costs for HEE [34]. For example, a pricing authority or a health economist may calculate the cost of a specific DRG by summing the cost of its standardised resource bundle (hours of operating time, medical device, number of hospital days) valued with average costs of each component to arrive at the reimbursement tariff or the unit cost of the specific healthcare service. Similarly, for general healthcare services, it may be used to set national tariffs for non-DRG services, such as a fixed fee for a dialysis session. The data for this method can come from standardised unit costing approaches and databases, costing studies, treatment protocols, and clinical guidelines that define typical resource bundles. This method gives a balance between detail and practicality for system-wide payment.

Top-down Mikro-Costing: Standardisierte Kosten für Aktivitäten (z. B. DRG-Bewertung) → Balance zwischen Detail & Praktikabilität

Top-Down Macro-Costing

The goal of top-down macro-costing is to obtain a quick, high-level estimate of cost per unit (e.g., per visit, per procedure or other healthcare services). This method starts with a large, pre-existing financial total, such as a hospital's annual inpatient budget or expenses for general GP consultations [88]. This total is then divided by a simple volume metric – like the total number of patient discharges – to calculate an average cost per unit [71]. Top-down macro-costing is characterised by low precision and low accuracy, if highly aggregated data is used. For example, the estimate does not distinguish between a complex cardiac case and a simple maternity stay, or between a simple GP visit or a visit for a diabetes patient, who is more complex. The reliance on broad allocations means it rarely reflects true resource consumption [71]. Consequently, the approach's role in the context of DRGs and tariffs is limited. It can only be used to retrospectively assign total costs to a DRG category based on its share of patient volume. The resulting average is best used for rough comparison against national

Top-down Makro-Costing: Gesamtausgaben pro Volumen (z. B. KH-Budget / Entlassungen) → Geringe Präzision & Genauigkeit (nur grobe Näherung für Unit Costs)

tariffs rather than for setting them or as a proxy of unit costs in HEE, if no other unit cost is available. However, the availability of data is usually fast and cheap but fundamentally imprecise [34].

Bottom-Up Macro-Costing

Usually, the goal of bottom-up macro-costing is to create a (total) cost estimate to inform BIA or healthcare planning. The approach builds on broad estimates for resource consumption and specific unit costs. For example, a health economist or a planner might estimate that for a DRG case a patient will stay a specific amount of days and use x hours of operating room time, then apply hospital-internal average unit costs or prices from publicly available price lists to calculate a total cost [34, 71, 88]. This approach results in low precision and low-to-moderate accuracy, as its outputs are highly dependent on the quality of its initial estimates.

Bottom-up Makro-Costing: Grobe Ressourcenmengen (z. B. Tage, OP-Stunden) x spezifische Unit Costs → geringe Präzision und Genauigkeit abhängig von Eingangsschätzungen

3.3 Quality Criteria for Cost Estimates and Estimators

3.3.1 General Quality Criteria for Estimates

Costing is an estimation process. Cost estimates, whether for total expenditure, unit cost, or average cost[12], are typically expressed as point estimates. Any estimate or estimator (estimation method) and therefore the costing process should meet core quality criteria to be considered "good". Although no complete, validated list of quality criteria exists [90], general statistical standards [91, 92], EbM checklists [93, 94] and quality frameworks [95] define the key attributes of a high-quality estimate or estimator. These include:

Qualitätskriterien:

Kostenerfassung ist eine Schätzung

allg. Qualitätskriterien:

- Unbiasedness/Accuracy: Expected value (estimate) equals true parameter. — Unverzerrtheit
- Efficiency/Precision: Estimate has minimal variance among unbiased estimators. — Effizienz/Präzision
- Consistency: Estimate converges to true value as sample size increases. — Konsistenz
- Robustness: Estimate is insensitive to violations of assumptions. — Robustheit
- Sufficiency: Estimator uses all relevant information in data. — Suffizienz
- Directness: Generalisability to target population. — Direktheit

3.3.2 Quality criteria in the health economic context

Frameworks, including checklists and guidance documents, in the HEA and HTA context implicitly and explicitly define criteria for the quality of estimates and estimation methods. The most popular and applied frameworks in the health economic context are:

Qualitätskriterien in ges.ök. Frameworks

[12] The term unit cost refers to the cost of a defined service unit and can be estimated using various approaches. While the average cost is commonly used as a practical proxy, its representativeness depends on the underlying cost distribution. For decisions about scaling or changing output, the marginal cost may be a more relevant unit cost measure.

- Consolidated Health Economic Evaluation Reporting Standards (CHEERS/CHEERS checklist) by Husereau et al. [2022]. — CHEERS
- European Network for Health Technology Assessment (EUnetHTA) HTA Core Model® [20]. — EUnetHTA Core Model
- BMJ Guidelines for Economic Evaluations by Drummond and Jefferson [1996][1]. — Drummond-Checkliste
- The Professional Society for Health Economics and Outcomes Research formerly known as Internatoinal Society for Pharmacoeconomicss and Outcomes Research (ISPOR) Principles of Good Practice for Budget Impact Analysis I [23] and II [24]. — ISPOR Good-Practice BIA
- Good Practice Guidelines for Decision-Analytic Modelling by Philips et al. [2006]. — Modellierungsleitlinien von Philips et al.

The application of such frameworks ensures that the data inputs, outputs and methods used in HEA, such as cost-effectiveness analyses, BIA, and other HEA are transparent, reliable, and methodologically sound. The estimation of unit costs applied in the costing process should also adhere to such criteria. — Frameworks sichern Transparenz, Reliabilität & methodische Qualität von Daten & Methoden

Table 3-4 provides an overview of 10 relevant quality criteria for cost data[13], sourced and derived from the five above listed publications relevant for HEA. The criteria do not only apply to costs presented in HEA, but also to estimated unit cost used in the costing process of a HEA and the estimation approaches to arrive at the used unit cost.

[13] The criteria simultaneously apply to outcomes such as estimated quality-adjusted life years or clinical endpoints but are presented specifically for cost data.

Table 3-4: Quality criteria for assessing the quality of cost estimates and estimation methods

Criterion	Description and meaning of criterion
Accuracy (Internal Validity) & Unbiasedness	A (cost) estimate is accurate or unbiased, if the expected value (the estimate) equals the true population parameter. Higher accuracy means the estimate is less affected by systematic bias, thereby minimising consistent deviations from the actual (cost) value, time, or resources used [92].
Precision	A cost estimate is precise if the estimate has minimal variance among unbiased estimators. A more precise estimate reduces uncertainty[14] but requires more effort, e.g., more cost data or a more refined (decision-analytic) model [96].
Uncertainty, Risk Awareness & Flexibility	Cost estimates should account for uncertainties[14] and potential variations. Considering uncertainty in cost estimates allows for flexible adjustment to other settings. Point (cost) estimates are reported with interval estimates (e.g., confidence intervals). Furthermore, non-normal distribution of cost may be an issue as well. Cost data are typically very right-skewed with variance increasing with greater survival time (heteroskedasticity) [97, 98].
Reliability & Comparability	Reliability pertains the consistency of estimated costs when repeated under similar conditions. It is also related to precision [92, 96]. This criterion ensures that the estimation method produces stable results, whether repeated by the same person or conducted by different people. Reliability also concerns the extent to which different cost estimates for different intervention or health services components share common defining elements. Variability between cost estimates for different interventions should depend on included resources, time horizon, and perspective.
Generalisability & Directness (External Validity)	Generalisability refers to the extent to which an estimated costs can be directly applied across different interventional or health care settings, populations, health systems, countries, and times periods. Factors that may limit generalisability include costs and benefits arising solely from a clinical study (and not occurring in real-world practice) or unrealistically high compliance rates [21]. For example, one might ask: *Are cost estimates from other EU countries applicable to Austria?*
Transferability	Transferability overlaps with generalisability but puts more emphasis on the actual adaptation effort and adjustment modalities. Cost estimates from another setting, country, or time point are usually adjusted for inflation, purchasing power parity (PPP), and currency. The choice of the discount rate should also be explicitly justified [21, 53].
Transparency (Traceability & Documentation)	A clear documentation, i.e. the comprehensive and transparent recording of assumptions, methods, and data sources, is essential so stakeholders can understand how costs were estimated (Traceability). Traceability is the ability to track how each component of the cost estimate was derived. Transparency in reporting is a requirement to assess the generalisability and transferability of estimates from one setting to another [21, 23, 24].
Credibility	Cost estimates should be trusted by stakeholders and reflect current practice, based on expert judgment, historical data, or validated models [25]. Credible cost estimates should be derived from best available data sources and thoroughly referenced to support transparency and replication. Validation of cost data is also an important pillar. Cost data from one country or setting may not be credible in another [23].
Completeness	The cost estimate should cover all necessary resources (e.g., labour, materials, overheads) and avoid missing critical cost or time components. Any missing or hard-to-specify cost and resource components should be reported [53].
Realism including Cost-Effectiveness & Timeliness	Realism is closely connected to generalisability, transferability, and credibility, but realism also considers whether the effort invested in producing the estimate is justified by its benefits. Cost-effective estimates strike a balance between effort and accuracy, remain feasible and avoid overly optimistic/pessimistic assumptions ("conservative" [21]). Furthermore, the estimate should be available when needed for decision-making, acknowledging that early estimates may be less accurate but still useful for initial planning.

Verankerung der Qualitätskriterien in den Frameworks

Table 3-5 illustrates how fundamental quality criteria are anchored within the structure of five popular health economic frameworks. By locating where criteria such as precision and completeness are specified, the table provides direct evidence that these attributes are considered indispensable by methodological standards for generating cost data that is fit for health economic decision-making.

[14] Briggs et al. [2012] provide an overview of the different uncertainty concepts (stochastic uncertainty/first-order uncertainty, parameter uncertainty/second-order uncertainty, heterogeneity/variability, structural/model uncertainty).

Table 3-5: Overview of quality criteria, affected domain, and publication

Criterion	CHEERS Checklist [99]	EUnetHTA HTA Core Model® [20]	BMJ Guidelines for Economic Evaluations [21]	ISPOR Principles of Good Practice for Budget Impact Analysis [23, 24]	Good Practice Guidelines for Decision-Analytic Modelling [25]
Accuracy (Internal Validity) & Unbiasedness	Methods & Results (e.g., Measurement & Valuation of Resources & Costs; Study Parameters etc.)	Clinical Effectiveness; Safety; Costs & Economic Evaluation (Biases, Confounding Factors, Level of Evidence; Model validation)	Data Collection (Effectiveness Data & Costing); Analysis and Interpretation of Results	Inputs & Data Sources	Data inputs
Precision	Methods & Results (e.g., Currency, Price Date & Conversion; Study Parameters etc.)	Clinical Effectiveness; Costs & Economic Evaluation (Tools for Critical Appraisals)	Analysis & Interpretation of Results (Allowance for Uncertainty)	Analytical Framework (General; Perspective; Validation)	-
Uncertainty, Risk Awareness & Flexibility	Uncertainty Analysis; Heterogeneity; Analytics & Assumptions	Clinical Effectiveness; Costs & Economic Evaluation (Model-based Economic Evaluation; Characterising Uncertainty)	Data Collection (Modelling); Analysis & Interpretation of Results (Allowance for Uncertainty)	Analytical Framework (Uncertainty and Scenario Analysis); Inputs & Data Sources (Ranges and Alternative Values for Uncertainty and Scenario Analyses); Reporting Format (Study Design and Methods; Results)	Data (Assessment of Uncertainty)
Reliability & Comparability	Methods (e.g., Comparators, Perspective; Time horizon; Setting & Location etc.)	Clinical Effectiveness; Costs & Economic Evaluation (Analysing & Synthesising Evidence	Study Design (Selection of Alternatives); Data Collection	Analytical Framework (Validation); Inputs & Data Sources (General)	Consistency (Internal Consistency; External Consistency; Predictive Validity); Model Structure (Comparators)
Generalisability (External Validity)	Methods (e.g., Setting & Study Population etc.	Clinical Effectiveness & Costs & Economic Evaluation (Characterising Uncertainty)	Data Collection (Effectiveness Data & Study Population; Costing); Presentation of Results	Analytical Framework (General; Indirect Costs)	Consistency (External Consistency; Predictive Validity)
Transferability	Methods (Setting & Location; Reporting in Abstract, Introduction & Discussion)	Clinical Effectiveness; Costs & Economic Evaluation (Characterising Uncertainty; Transferability including EU-wide applicability and multi-country focus)	Data Collection (Effectiveness Data & Study Population; Costing); Analysis & Interpretation of Results (Presentation of Results)	-	-
Transparency and Traceability	All domains (e.g., Results. Discussion etc.)	Costs & Economic Evaluation (Reporting & Interpreting)	Data Collection (Modelling) & Analysis and Interpretation of Results (Presentation of Results)	Analytical Framework (Use & Cost of Current and New Interventions); Inputs & Data Sources (General); Reporting Format (General; Results)	Data (Data Identification & Incorporation); Structure (Structural Model Assumptions)
Credibility	Discussion & Other Relevant Information (Limitations, Source of Funding, Conflict of Interest etc.)	Organisational Aspects (Quality Assessment of Expert Opinion; Conflict of Interest)	-	Analytical Framework (Validation); Inputs & Data Sources (General)	Data (Data Identification/Expert Opinion)
Completeness	Methods (Measurement & valuation of resources & costs)	Costs & Economic Evaluation (Tools for Critical Appraisals)	Study design (Study Question)	Reporting Format (Conclusions & Limitations)	Data (Data Incorporation); Structure (e.g., Structural Assumptions; Perspective etc.)
Realism including Cost-Effectiveness & Timeliness[15]	-	Clinical Effectiveness & Costs & Economic Evaluation (Clinical validity)	Study Design (Study Question)	Analytical Framework (General/Design)	-

[15] Timeliness is not explicitly addressed in any of the frameworks and realism is often already addressed indirectly in the other domains.

3.3.3 Quality Criteria within the Costing Process

Qualitätskriterien im Kostenprozess

The preceding analysis of health economic frameworks reveals a consistent set of quality criteria. The criteria are practical necessities that find their purpose only when applied to the costing itself. The quality of any cost estimate is entirely dependent on the rigour applied at each stage of the costing process.

Identification of Resources

Qualitätskriterien im Identifikationsschritt

As mentioned, this step involves defining which resources are included (e.g., pharmaceuticals, medical devices, working time, patient travel costs) from a specified perspective (e.g., healthcare system, societal etc.). The following quality criteria are located in the identification stage:

- Completeness: All relevant resource categories based on the chosen perspective must be captured. Omitting significant costs (e.g., informal care or productivity costs in a societal perspective) irrevocably biases the result.

  Vollständigkeit: alle relevanten Ressourcen

- Directness: The identified resources must have a direct, logical link to the intervention and the clinical decision being evaluated. This ensures the estimate is relevant and avoids including extraneous costs.

  Direktheit: Zusammenhang mit Intervention

- Realism: The resources must reflect real-world clinical practice and pathways. An unrealistic identification of resources undermines the estimate's practical applicability.

  Realismus: Abbildung realer Versorgungspraxis

Resource Use Measurement

Qualitätskriterien im Messungsschritt

This stage involves quantifying the amount of each resource used (e.g., a specific number of hours of nursing care, a number of diagnostic tests, five hospital days etc.). The measurement phase has typically to satisfy the following:

- Accuracy (Internal validity) & unbiasedness: The quantified volumes must be correct and derived without systematic error. This requires robust data collection methods that are not skewed by selection bias or measurement bias. An accurate but biased measurement will consistently over- or under-estimate the true resource use.

  Genauigkeit (Validität) & Unverzerrtheit: kein systematischer Fehler

- Precision: This refers to the reliability and fineness of the measurement. High-precision data has low random variability. Precise measurements, e.g. the necessary time to complete a task, reduce the uncertainty around the mean estimate.

  Präzision: geringe Zufallsvariabilität

- Transparency (Traceability & documentation): Every used resource must be fully documented with a clear source to reflect the real cost in terms of resource use.

  Transparenz: nachvollziehbare Quellen & Dokumentation

Valuation of Resources

Qualitätskriterien im Bewertungsschritt

This stage involves attaching unit costs (e.g., hourly wage rate, drug price per mg) to the measured resource quantities. The following quality criteria are essential at this stage:

- Transparency (Traceability & documentation): This criterion also applies to the valuation stage. Every unit cost must be fully documented with a clear source, year, and any adjustments made (e.g., inflation

  Transparenz: Dokumentation von Quelle, Adaptionen, Jahr

adjustments, currency conversions, conversions from DRGs to economic costs).

- Credibility: The sources for unit costs must be authoritative and appropriate (e.g., national tariff schedules, established costing databases, peer-reviewed publications). Using dubious or non-representative sources destroys the trust in the final estimate.

Glaubwürdigkeit: Autoritative, angemessene Quellen

- Realism including cost-effectiveness: The valuation must use relevant and current prices. Furthermore, the effort invested in sourcing and developing highly granular costs must be cost-effective itself, balancing the gain in precision with the resources required to obtain it.

Realismus & Effizienz: aktuelle Unit Cost, Verhältnismäßigkeit Genauigkeit & Aufwand

Overarching Criteria of the Entire Costing Process and Final Estimate

The following criteria cover the entire costing process.

prozessübergreifende Kriterien:

- Uncertainty, risk awareness & flexibility: Uncertainty is embedded in the entire costing process – from variability in resource use to fluctuations in unit cost. A high-quality estimate proactively addresses this by conducting sensitivity analyses (e.g., probabilistic sensitivity analysis) to test the impact of these uncertainties. This demonstrates risk awareness and makes the model flexible for exploring different scenarios.

Unsicherheit: Sensitivitätsanalysen testen Einflüsse

- Reliability & comparability: When the entire process is transparent, complete, and based on accurate measurements, the estimate becomes reliable. Decision-makers or other health economists could follow the same process and reach a similar result. This also establishes the foundation for comparability with other estimates.

Reliabilität & Vergleichbarkeit: reproduzierbare Ergebnisse

- Generalisability & transferability: An estimate has higher value if its findings extend beyond the immediate study context. Generalisability is the extent to which the results can be applied to broader populations, while transferability refers to its applicability to a specific other setting. These properties are only possible if the initial costing process was thoroughly documented (transparency) and based on realistic, well-justified assumptions (realism, credibility).

Generalisierbarkeit: Anwendbarkeit auf andere Populationen/ Kontexte

- Realism including cost-effectiveness & timeliness: The entire costing process must reflect current practices. Furthermore, the effort of the whole costing process must be cost-effective itself. The level of precision is directly contingent upon the methodological effort (micro- versus macro-costing), establishing a fundamental trade-off. The whole costing process must also be delivered in a timely manner to be useful for decision-making.

Realismus, Effizienz & Aktualität: Methodenaufwand angemessen, Ergebnisse zeitnah & praxisrelevant

In summary, quality criteria guide each step of the costing process. From ensuring nothing is missed during identification, to guaranteeing reliable measurement and credible valuation, these criteria work together to produce an estimate that is not just a number, but a scientifically rigorous and policy-relevant piece of evidence.

Qualitätskriterien leiten gesamten Kostenprozess → wissenschaftlich fundierte & policy-relevante Evidenz

4 Country and Guideline Overview

4.1 General Overview of Countries and Identified Documents

The included guidelines from the 12 countries show a robust core of methodological consensus for the reference case (base case), alongside distinct national characteristics that reflect differing healthcare systems and policy priorities. All the following guideline aspects have a direct impact on the costing process and the considered costs (and outcomes).

Länderübersicht (n=12): grober methodischer Konsens bei Referenzmethoden, aber nationale Unterschiede

4.1.1 Document Type, Scope, and Regulatory Mandate

Document Type and Scope

A clear commonality of the identified countries is the production of comprehensive methodological guidance. Most of the included countries have developed dedicated HEE guidelines, often accompanied by separate or integrated guidance for BIA and separate costing manuals (e.g., Australia [31, 32], Belgium [33, 34], Canada [35-37], the Netherlands [49, 50]). The remainder of the countries provide Health Technology Assessment guidelines, which integrates economic evaluation as a core component within a wider assessment of clinical effectiveness, safety, organisational and budget impact (e.g., Australia [31, 32], England & Wales [42], Germany [44], Norway [47], Scotland [48]).

Dokumententyp & -umfang:

Dokumententyp variiert

The type of technology the guidelines address varies. Several, like those in Australia [31, 32], Denmark [38-41], Scotland [48], and New Zealand [45, 46], are primarily focused on pharmaceuticals. In contrast, guidelines from Belgium [33, 34], Canada [35-37], France [43], the Netherlands [49, 50], and the USA [51, 52] explicitly cover all types of health technologies, including medical devices, diagnostics, and procedures. Germany's HTAG, while mainly applied to pharmaceuticals, can be understood as a gold standard for evidence assessment in Germany and is also used by the IQWiG when conducting "in-house" health economic evaluations for non-drug interventions (e.g., surgeries, screening, disease management programs) [44].

Technologieumfang variiert:

teils nur Arzneimittel (AUS, DNK)

teils alle Technologien (BEL, CAN, FRA, NDL, USA)

Stringency and Regulatory Status

The regulatory mandate of these guidelines differs across countries. The majority of the guidelines are mandatory for submissions to national reimbursement or pricing authorities (Australia [31, 32], Belgium [33, 34], Denmark [38-41], France [43], Scotland [48], Netherlands [49, 50]). Others are considered de-facto mandatory due to their role in the assessment process (Canada [35-37], Germany [44], New Zealand [45, 46]). While these de-facto mandatory guidelines may not have a strict legislative statute, adherence is essential for a positive reimbursement recommendation.

Mehrheit verpflichtend für Erstattungsanträge; andere de-facto verpflichtend

An exception is the guideline for England & Wales [14], which is not mandatory, and the guideline by the Institute for Clinical and Economic Review (ICER), a US non-governmental organisation [51, 52], which is recommendatory and used to inform stakeholder discussions rather than for direct regulatory submission.

England & Wales (nicht verpflichtend), USA (empfehlend)

Table 4-1 gives an overview of the identified guideline documents including information on the focus and regulatory status.

Table 4-1: Overview of guideline documents including information on guidance issuing body, focus, and regulatory status

Country	Guidance issuing body ("HTA agency/body")	Document type(s)	Focus of guidelines	Stringency & Regulatory status of guidelines
Australia [31, 32]	Pharmaceutical Benefits Advisory Committee (PBAC)	HTAG + CM	Pharmaceuticals	Mandatory for submissions
Belgium [33, 34]	Belgian Health Care Knowledge Centre (KCE)	HEEG incl. BIAG + CM (Hospital)	All types of health technologies	Mandatory for submissions and universal guideline
Canada [35-37]	Canadian Agency for Drugs and Technologies in Health (CADTH)	HEEG + BIAG + CM	All types of health technologies	De-facto mandatory[16] for submissions and universal guideline
Denmark [38-41]	Danish Medicines Council (DMC)	HEEG + CM	Pharmaceuticals	Mandatory for submissions
England & Wales [42]	National Institute for Health and Care Excellence (NICE)	HTAG	All types of health technologies	Not mandatory
France [43]	French National Authority for Health (HAS)	HEEG	All types of health technologies	Mandatory for submissions[17]
Germany [44]	Institut für Qualität und Wirtschaftlichkeit im Gesundheitswesen (IQWiG)	HTAG	Pharmaceuticals (mainly)	De-facto mandatory[18] for submissions by pharmaceutical companies
New Zealand [45, 46]	Pharmaceutical Management Agency (PHARMAC)	HEEG incl. BIAG + CM	Pharmaceuticals	De-facto mandatory for submissions and universal guideline
Norway [47]	Norwegian Medical Products Agency (NoMA)	HTAG	Pharmaceuticals and medical devices[19]	Mandatory for submissions

[16] The Canadian HEEG is not legally mandatory but is functionally mandatory for developers wishing to secure reimbursement from Canadian public payers.

[17] The guideline is binding for companies submitting a technology to HAS for reimbursement, but not for academic research or hospital internal decisions. However, it is considered the primary reference for methodological quality in France.

[18] *"According to §139a (4) Sentence 1 SGB V, the Institute is legally obliged to ensure the "assessment of the medical benefit [of interventions] following the internationally recognized standards of evidence-based medicine and the economic evaluation following the relevant internationally recognized standards for this purpose, in particular of health economics". Depending on the commission, the Institute determines the methods and criteria for the preparation of assessments on the basis of the international standards of evidence-based medicine (EbM) and health economics recognized by the relevant experts."* – Institut für Qualität und Wirtschaftlichkeit im Gesundheitswesen (IQWiG) [2025, p.4].

[19] The Norwegian Medicines Agency (NoMA) is the primary body for HTAs of pharmaceuticals – so called Single Technology Assessments (STAs) for medicinal products. Since January 2024, it also conducts HTAs for medical devices, but only when commissioned by the national New Methods (Nye metode) system. While the HTA process for devices shares core methods with medicinal products, slight differences exist in the submission guidelines, particularly regarding the costing of medical devices including diagnostic products and capital costs.

Scotland [48]	Scottish Medicines Consortium (SMC)	HTAG	Pharmaceuticals[20]	Mandatory for submissions
Netherlands [49, 50]	Zorginstituut Nederland (ZIN)	HEEG + CM	All types of health technologies	Mandatory for submission and for assessments by ZIN
USA [51, 52]	Institute for Clinical and Economic Review (ICER)	HEEG + BIAG	All types of health technologies	Recommendatory guideline

BIAG…Budget Impact Analysis Guideline, CM…Costing Manual, HEEG…Health Economic Evaluation Guideline, HTAG…Health Technology Assessment Guideline

4.2 Costing-Specific Aspects in Identified Documents

4.2.1 Analytical Approach and Perspective(s)

Type of Analysis

CUA als Referenzmethoden-Goldstandard, aber auch Flexibilität (e.g., CEA & CMA bei Äquivalenz)

All included guidelines recommend a cost-utility analysis (CUA) as the preferred and often required form of evaluation for the reference case. While CUA is the gold standard, some guidelines show flexibility: France [43] and Germany [44] also accept cost-effectiveness analyses (CEA) in submission. Some jurisdictions permit submissions based on a limited analysis, such as cost-minimisation (CMA) for therapeutic equivalence in Australia [31, 32], Belgium [33, 34], France [43], Norway [47], and Scotland [48], cost-consequence analysis (CCA) in England & Wales[21] [42] and Denmark, or even a cost analysis (CA) in Denmark [38-41].

Table 4-2: Overview of recommended analysis types in each country

Approach	AUS	BEL	CAN	DKN	E&W	FRA	GER	NZL	NOR	SCT	NDL	USA
CUA	✓*	✓*	✓*	✓*	✓*	✓*	✓*	✓*	✓*	✓*	✓*	✓*
CEA	X	X	X	X	X	✓	✓	X	X	X	X	X
CBA	X	X	X	X	X	X	X	X	X	X	X	X
CMA	(✓)	(✓)	X	X	X	(✓)	X	X	(✓)	(✓)	X	X
CCA	X	X	X	(✓)	(✓)	X	X	X	X	X	X	X
CA	X	X	X	(✓)	X	X	X	X	X	X	X	X

✓…Analysis applied

**Preferred approach in each country (reference case)*

(✓)…Permitted in certain circumstances

X…Not applied

[20] The Scottish Medicine Consortium's (SMC) assessment is limited to Prescription Only Medicines (PoMs). Devices containing medicines that lack marketing authorization by the Medicines and Healthcare products Regulatory Agency (MHRA) are excluded. Further exclusions include public health vaccines, generic medicines, blood products (with specified exceptions), diagnostics.

[21] Cost-comparison (CC) should be used only for technologies offering similar health benefits at similar/lower costs than NICE-recommended comparators for the same population.

AUS…Australia, BEL…Belgium, CA…Cost-analysis, CAN…Canada, CBA…Cost-Benefit Analysis, CCA…Cost-Consequences Analysis, CEA…Cost-Effectiveness Analysis, CMA…Cost-Minimisation Analysis, CUA…Cost-Utility Analysis, DKN…Denmark, E&W…England & Wales, FRA…France, GER…Germany, NZL…New Zealand, NOR…Norway, SCT…Scotland, NDL…the Netherlands, USA…United States of America.

Analytical Perspective in the Reference Case

Perspektive

The choice of perspective is a fundamental determinant of which costs (and outcomes) are included and reflects a philosophical divide in HEA.

Mehrheit: Gesundheitssektor

The healthcare system or payer perspective is the most commonly recommended approach, used in Australia [31, 32], Belgium [33, 34], Canada [35-37] (publicly funded payer), New Zealand [45, 46], England & Wales (NHS and Personal Social Services [PSS] perspective) [42], Scotland (Healthcare system and PSS perspective) [48], Germany (social health insurance [SHI] - insured community) [44], New Zealand (publicly funded payer) [45, 46] and the US [51, 52].

Minderheit: gesellschaftlich/quasi-gesellschaftlich inkl. Produktivitätskosten & informeller Pflege

A significant minority of countries mandate a societal or quasi-societal perspective requiring the inclusion of indirect costs such as productivity losses and informal care. This group includes Denmark [38-41], France [43], Norway [47], and the Netherlands [49, 50]. The French guideline [43] also permits a healthcare system perspective instead of a societal one, provided the choice in the reference case analysis is justified. Some jurisdictions recommend complementary analyses to reflect broader impacts beyond the health-care system. The US guideline [51, 52] proposes a hybrid modified societal perspective, which includes some productivity costs but may not be as comprehensive as a full societal analysis. A similar approach applies to Australia [31, 32].

4.2.2 Evidence and Modelling

Data Sources and Hierarchy

Datenquellen & Hierarchie:

RCTs, SR, Meta-Analysen ,aber oft ergänzungsbedürftig (begrenztes Follow-up, restriktive Populationen)

alle Quellen:

All guidelines establish a clear hierarchy of evidence for clinical effects that may also inform economic models, with systematic reviews (SR), meta-analyses, randomised controlled trials (RCTs) universally preferred to establish internal validity and efficacy [33, 35, 44, 47, 49]. Some guidelines explicitly limit or exclude non-RCT evidence (e.g., observational or unpublished data) for establishing effectiveness[22]. However, most guidelines acknowledge that RCTs alone are often insufficient for a full economic evaluation due to limited follow-up, restrictive patient populations, and use of surrogate endpoints. Consequently, identified guidelines commonly permit and often require the synthesis of multiple evidence sources:

[22] The Belgian guideline states that observational data (registries/administrative databases) cannot be used to establish therapeutic benefit (due to the lack of randomisation); but are appropriate for valuing economic inputs. In Denmark, clinical efficacy and safety evidence should come from peer-reviewed journal articles, European Medicines Agency (EMA) European public assessment reports (EPARs), Food and Drug Agency (FDA) reports, or HTAs. However, the DMC may accept unpublished sources when these allow the HEA to better reflect the specific context of the application than would be possible using published data alone.

- For long-term extrapolations: SRs, meta-analyses, and registry data to inform long-term outcomes, mortality, and safety in real-world populations [31, 38, 42, 43, 45, 48].
- For pragmatic model inputs: non-randomised intervention studies, observational studies and routine practice data collection from registries (RPDC) where needed [44].
- For real-world effectiveness: Observational studies from registry studies or so-called real-world data (RWD) to complement RCT data, capturing effectiveness in routine clinical practice and in broader patient subgroups [38, 42, 43, 45].

SR, Meta-Analysen, Registerdaten

nicht-randomisierte Studien

RWD/Register zur Ergänzung von RCTs

In addition, for cost and resource use parameters, national administrative databases, registries, unit cost catalogues, (national) tariffs and fee schedules are the standard and expected sources across all countries [31, 33-52], ensuring that analyses reflect local clinical practice and pricing. Detailed sources for measurement and valuation of resources and costing domains are described in the Section 4.4 Costing Process Step II: Resource Use Measurement and 4.5 Costing Process Step III: Valuation of Resources and Costing Domains.

Kostendatenquellen:

administrative Datenbanken, Register, Unit Cost- & Tarif-Kataloge

The Role of Modelling

Although some guidelines recommend trial-based HEE as primary health economic evidence (Belgium, Canada[23], Denmark), model-based economic evaluations are not only accepted but are often the default expectation. The rationale for modelling is consistent across guidelines:

modell-basierte Evaluationen oft Standard

- To extrapolate beyond the trial period to capture lifetime costs and outcomes [42, 49].
- To synthesise evidence from multiple sources into a coherent framework [37, 43].
- To compare all relevant treatment options, including those not compared head-to-head in a single trial [43].
- To adapt clinical trial data to reflect real-world clinical pathways and specific national contexts [44].

Some guidelines provide explicit directives. Germany's guideline [44] states that a decision-analytic model is usually necessary because clinical studies rarely contain all required information. The Norwegian guideline [47] emphasises that models must be fully adjustable for key parameters (e.g., time horizon and subgroups), ensuring transparency and flexibility for assessment.

Anpassung an nationale Kontexte notwendig

Time and Uncertainty

Time Horizon and Discounting

A universal principle is that the time horizon must be long enough to capture all relevant differences in costs and outcomes between technologies. For chronic diseases or life-prolonging therapies, a lifetime horizon that includes relevant future costs is typically required. Some countries include all future healthcare consumption due to extended life in their time horizon – so called unrelated future costs. Some guidelines state that the time horizon should

Zeithorizont & Diskontierung: Lebenszeithorizont, um alle relevanten Kosten- & Outcomeunterschiede zu erfassen

[23] The Canadian guidelines primarily address model-based HEE; however, many provisions, such as choice of outcome, apply equally to evaluations based on individual-level studies (e.g., RCTs).

only include future costs and consequences of the specific decision at hand (see Future Cost and Future Cost Changes for details).

divergente Diskontierung: unterschiedliche Bewertung intergenerationaler Gerechtigkeit

The main methodological variation concerns the discount rate. As shown in Table 4-3, rates vary from 1.5% to 5%. This variation is not arbitrary as it reflects different national economic circumstances, social time preferences of costs and benefits, and ethical views on intergenerational equity.

The application of discounting reveals three broad approaches:

- Uniform discounting: Most countries (Australia, Denmark, England & Wales, France, Germany, New Zealand, Norway, Scotland, USA) apply a single rate to both costs and outcomes, based on the opportunity cost of capital and general future uncertainty.

einheitliche Diskontierung

- Differential discounting: Belgium [33, 34] and the Netherlands [49, 50] apply a differential rate (e.g., 3% for costs, 1.5% for outcomes). This practice is rooted in the Ramsey rule[24] and the ethical argument that society may value future health gains more highly than future monetary costs, implying a lower social time preference for health.

differenzielle Diskontierung (Ramsey Regel)

- Tiered discounting: France [43] and Norway [47] have uniquely tiered approaches that decrease the discount rate over very long time horizons (beyond 30-40 years), reflecting the view that increasing long-term uncertainty warrants lower discounting of distant cost and outcomes.

gestaffelte Diskontierung

Table 4-3: Discount rates in the reference case of each country

Country	Discount rate: Costs	Discount rate: Outcomes
Australia [31, 32]	5%	5%
Belgium [33, 34]	3%	1.5%
Canada [35-37]	1.5%	1.5%
Denmark [38-41]	4%	4%
England & Wales [42]	3.5%	3.5%
France [43]	2.5% (for t ≤30 y) / 1.5% (for t >30 y)	2.5% (for t ≤30 y) / 1.5% (for t >30 y)
Germany [44]	3%	3%
New Zealand [45, 46]	3.5%	3.5%
Norway [47]	4% (1-40 y), 3% (41-75y), 2% (t >75y)	4% (1-40y), 3% (41-75y), 2% (t >75y)
Scotland [48]	3.5%	3.5%
Netherlands [49, 50]	3%	1.5%
USA [51, 52]	3%	3%

t…time, y…year(s)

[24] The Ramsey rule states that the discount rate should reflect pure time preference and the diminishing marginal utility of (health) consumption over time. This logic is extended to health economics to justify discounting health outcomes at a lower rate than costs, based on the argument that society has a very low, or even zero, pure time preference for future health gains.

Handling Uncertainty: Sensitivity Analysis

Bewertung Unsicherheit in methodischer Standard

The comprehensive assessment of uncertainty in costs and outcomes is a baseline requirement across guidelines, reflecting a high degree of methodological maturity in all guidelines.

deterministische Sensitivitätsanalyse zum testen von strukturellen Unsicherheit (z. B. Diskontraten, Zeithorizonte, Behandlungspfade)

Deterministic sensitivity analysis (DSA) is universally mandated as a foundational step. All guidelines require one-way or multi-way sensitivity analyses to identify key drivers of the model's results by testing the impact of varying individual parameters over plausible ranges [31, 43, 44, 47]. Many guidelines (e.g., Australia [31, 32] and Germany [44]) require testing key methodological assumptions, such as varying discount rates (e.g., 0% vs. 5%) or time horizons, via sensitivity analysis. In addition, a majority of guidelines (e.g., Australia [31, 32] and France [43]) explicitly require scenario analysis to explore the impact of structural uncertainty (e.g., alternative modelling approaches or treatment pathways).

probabilistische Sensitivitätsanalyse ermöglicht Analyse der „Gesamtunsicherheit"

Probabilistic sensitivity analysis (PSA) is also widely expected, often encouraged or mandated (e.g., Belgium [33, 34], Canada [35-37], and England & Wales [42]). PSA quantifies the overall decision uncertainty by propagating joint parameter uncertainty and supporting calculation of cost-effectiveness acceptability curves (CEACs). This is considered best practice for characterising parameter uncertainty.

weitere Techniken

Beyond DSA and PSA, specific guidelines incorporate more advanced techniques.

- Value-of-Information-Analyse: quantifiziert „Wert" weiterer Forschung zur Unsicherheitsreduktion.

  The Netherlands [49, 50] and Belgium [33, 34] explicitly recommends Value of Information (VOI) analysis to quantify the economic value of reducing uncertainty through further research. VOI analysis includes two key subtypes: the Expected Value of Perfect Information (EVPI) and the Expected Value of Partial Perfect Information (EVPPI). VOI is an extension of probabilistic analysis designed to quantify the potential benefit of conducting additional research – or, conversely, the expected cost of making decisions based on existing, imperfect evidence [100]. This directly informs decisions about research prioritisation and managed entry agreements.

- ICER-Schwellenwertanalyse in manchen Leitlinien

  Some guidelines (Australia, Canada, England & Wales, Netherlands, Norway, Scotland, USA) recommend an incremental cost-effectiveness ratio threshold[25] analysis. For example the US frames results against a specific cost-per-QALY range ($ 50,000-200,000), linking (methodological) uncertainty to a deliberative framework for value [51, 52].

4.2.3 Costing-specific Aspects in Budget Impact Analysis

Budgetfolgenanalyse (BIA) in fast allen Ländern Pflicht

BIA is a mandatory or expected in virtually all included jurisdictions to determine the affordability in addition to cost-effectiveness. Common costing features across identified guidelines include a shorter time horizon compared to HEE, typically three to five years, aligned with budgeting cycles of health systems and no discounting of costs and outcomes, as BIA concerns nominal, short-term financial flows.

[25] Strohmaier et al. [2025] provide an international overview of the operationalisation of incremental cost-effectiveness ratio thresholds.

BIA-Perspektive oft spezifischer als in ges.ök. Analysen (einzelne KH oder Regionen)

The perspective for BIA, however, is often more specific and fragmented than for the HEE, reflecting decentralised financial responsibilities in many healthcare systems. Examples include the hospital perspective in Denmark [38-41], the regional health authority perspective in Norway [47], and the commissioner perspective[26] in England & Wales [42]. Manufacturers may therefore need to present multiple, disaggregated budget impact estimates for a single country.

BIA-Ansatz

The preferred approach to define the potential BIA population varies across countries:

ausschließlich epidemiologisch

- Belgium [33, 34] and England & Wales [42] strictly specify an epidemiological approach.

epidemiologisch oder Marktanteil

- The guidelines in Australia[27] [31, 32], Canada [35-37], the USA [51, 52] prefer an epidemiological approach but a market share approach is also possible.
- The Danish guideline [38-41] permits either approach.
- Germany [44] explicitly requires an epidemiological approach for BIA, incorporating the expected uptake rate (market share).

ausschließlich Marktanteil

- The guidelines from New Zealand [45, 46] and Scotland [48] strictly specify a market-share approach.

Mehrheit favorisiert epidemiologischen Ansatz

Overall, guidelines tend to prefer the epidemiological approach. For the remaining three countries, no clear approach could be discerned from the available guidelines. BIA is not yet fully established in the Netherlands [49, 50, 103], and for France[28] [43] and Norway [47] no specific information were available.

länderspezifische BIA-Ansätze

Further unique national requirements are operationalised in the following countries:

- England & Wales [42] and Scotland [48]: Inclusion of value-added tax (VAT) in the BIA is explicitly required.
- Denmark [38-41]: Requirement to calculate impacts for multiple stakeholders, including patients, to ensure transparency about potential cost-shifting.
- Germany [44]: Only two BIA scenarios (status quo vs. new intervention) are required, simplifying analysis relative to jurisdictions that mandate multiple uptake scenarios.

[26] In contrast to NHS England (provider), an NHS commissioner plans, purchases, and monitors health services for a local population.

[27] A standardised Excel workbook and manual with the epidemiological approach is available on the PBAC guidelines website [101, 102].

[28] The French approach to estimate the target population for a BIA is not explicitly stated, but the HEEG indicates that a combination of both approaches should be conducted.

4.3 Costing Process Step I: Costing Approaches and Identification of Resources

4.3.1 Costing Approaches

Ressourcenidentifikation

Costing-Ansätze: Mehrheit ohne explizite Methodenangabe

Mischung aus Top-down-Makro & Bottom-up-Mikro-Costing

abhängig von Daten, Präzision, Perspektive

Regarding costing approaches, a majority (eight countries) of the twelve countries included do not explicitly report the foundational principles of their costing approach in the available guidelines (Australia, Canada, Denmark, France, New Zealand, Scotland, USA). However, there is strong, cross-national consensus on the foundational principle of costing: the objective to approximate opportunity cost[29] (see Definitions and Distinctions). To operationalise this, all countries employ a combination of top-down macro-costing and bottom-up micro-costing methods. According to the guidelines, the choice between these two approaches is universally guided by pragmatism – i.e., selecting a "fit-for-purpose" [35-37, 44] method given data availability, the required precision, and the analytic perspective. Some countries (Australia, France, Germany) also employ costing approaches beyond the top-down macro-costing and bottom-up micro-costing approaches (top-down micro-costing, top-down bottom-up macro-costing). Table 4-4 presents the costing approaches used in each country.

Table 4-4: Costing approaches used in each country

Approach	AUS	BEL	CAN	DKN	E&W	FRA	GER	NZL	NOR	SCT	NDL	USA
Top-down macro-costing	✓*	✓	✓	✓*	✓*	✓*	✓	✓*	✓*	✓[30]	✓	✓*
Bottom-up micro-costing	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓[30]	✓*	✓
Top-down micro-costing	✓	X	X	X	X	✓	✓	X	X	X	X	X
Bottom-up macro-costing	X	X	X	X	X	✓	X	X	X	✓[30]	X	X

✓…Approach applied

**…* Preferred approach in each country*

X…Not applied

AUS…Australia, BEL…Belgium, CAN…Canada, DKN…Denmark, E&W…England & Wales, FRA…France, GER…Germany, NZL…New Zealand, NOR…Norway, SCT…Scotland, NDL…the Netherlands, USA…United States of America.

Präferenz Top-down Makro-Costing für Mehrheit der Leistungen

The most significant commonality is the clear preference for top-down macro-costing as the default or primary approach for most standard costing domains (healthcare services, hospital services etc.). The use of predefined unit costs, such as per diem, per procedure, or or DRG-based unit costs/tariffs, is favoured for its practicality, consistency, and alignment with a health system perspective. It is extensively used for costing hospital services, healthcare

[29] While most countries do not explicitly cite the opportunity cost approach, their preferred methodologies for HEA (including HEE) are consistent with its principles.

[30] The top-down macro-costing approach to calculate average unit costs is complemented with a bottom-up resource identification approach for the patient pathway in de novo health economic evaluations.

services, and (non-novel) pharmaceuticals, forming the basis for national cost collections or (negotiated) reimbursement tariffs. This is explicitly or implicitly the preferred approach in the guidelines of Australia [31, 32], Belgium [33, 34], Denmark [38-41], England & Wales [42], France [43], New Zealand [45, 46], Norway [47], and the USA [51, 52].

Bottom-up-Mikro-Costing bei unzureichenden Unit Cost

Conversely, bottom-up micro-costing is applied where existing standard unit costs, tariffs, or other average cost information are deemed insufficient or inaccurate, notably for:

innovative Technologien

- New and innovative technologies (e.g., novel pharmaceuticals, medical devices, or surgical procedures) not yet covered by existing reimbursement schemes [33, 34, 44, 47] (Belgium, Germany, Norway).

„Kostentreiber"

- Cost components with high influence on the study's results, such as the incremental cost-effectiveness ratio [33, 34] (Belgium).

heterogene Leistungen mit variabler Ressourcennutzung

- Services with highly variable or patient-specific resource use, or where tariffs poorly reflect actual resource use and hence true economics costs [33, 34, 38-42] (Belgium, Denmark, England & Wales). The Danish guideline note that for precise economic impacts (e.g., drug-reduced hospitalisations), average cost proxies may lack precision and should be supplemented by micro-costing of individual service components [38].

länderspezifische Methoden:

While this hybrid, pragmatic model is the international norm, several countries have specific methodological characteristics.

NLD: Bottom-up-Mikro-Costing als Goldstandard

The Netherlands [49, 50] is a notable exception to the macro-costing preference. Its guidelines express a strong preference for bottom-up micro-costing as the gold standard, particularly for staff and client- or resident-related (i.e. patient-related) costs. The Dutch CM provides nationally agreed upon reference prices (unit costs) and standard calculation values[31] derived from bottom-up micro-costing studies to ensure consistency and efficiency, and to avoid time-consuming primary costing for common elements in economic evaluations. However, top-down macro-costing remains a supplement and default for general materials, food, other accommodation-related costs, other general costs, general medical equipment, or overhead costs.

BEL, E&W, SCT: Mix – primär nationale Tarife (Top-down-Makro), ergänzt durch Mikro (PLICS in England).

Belgium [33, 34], England & Wales [42], and partially Scotland [48] employ a broadly similar costing methodology mix to the Netherlands, but without naming a single method as the gold standard. All three countries rely primarily on national cost benchmarks (tariffs or national unit costs) by a mix of costing approaches: Belgium recommends Belgian per diem costs complemented by reimbursement tariffs from the National Institute for Health and Disability Insurance (RIZIV – INAMI)[32] database, while England & Wales and Scotland [48] provide a unit cost catalogue via the National Cost Collection (NCC), formerly NHS Reference Costs[33]. These unit costs are predominantly derived using a top-down macro-costing approach. In England &

[31] The standard calculation values are standardised cost units (e.g., bed-days, consultations) used to allocate resources and calculate actual costs, but they are not themselves the final cost price of a healthcare service.

[32] RIZIV-INAMI sets and publishes tariffs for medical treatments and services that are partly or wholly reimbursed by compulsory health insurance in Belgium.

[33] The term NHS Reference Costs is generally no longer applied in the healthcare context in the UK but still informally used. The concept has not been replaced but rather integrated in the more comprehensive NCC process. Instead, the term National Cost Collection Index (NCCI) is used [104].

Wales, the Patient-Level Information and Costing System (PLICS) progressively refines estimates by linking costs to individual patient pathways (a bottom-up micro-costing method) to supplement NCC's (average) unit costs. However, top-down macro-costing remains the recommended approach.

FRA: Bottom-up-Makro-Costing & Micro-Costing zur Aktualisierung von Unit Cost

The French [43] guidelines recommend a refined hybrid: Routine evaluations should measure patient-level resource use and value it using ATIH[34] national average unit costs – i.e., bottom-up macro-costing. Periodic micro-costing studies (e.g., for Homogeneous Patient Groups[35] [HPGs]) are used to construct and update these national averages, which then feed subsequent applications.

CAN, SCT, GER: flexible & pfadorientiert ("fit-for-purpose")

Scotland [48] and Canada [35-37] emphasise a pathway-oriented and flexible approach. In Scotland unit costs are calculated using top-down macro-costing[36] from the NHS Cost Book[37], similar to the Netherlands, Belgium, and England & Wales, but combining it with bottom-up resource identification for specific patient pathways, especially in new evaluations. Canada likewise promotes a pragmatic and flexible ("fit for purpose") approach aligned with the chosen perspective.

Germany [44] explicitly employs a pragmatic mix of costing methods. For each service, the method is chosen based on data availability and the level of precision required.

USA: Top-down-Makro; Mikro wo machbar

The US [51, 52] guideline recommends top-down macro-costing for calculating costs for pharmaceuticals, hospital and outpatient services, e.g., using DRG rates and the Medicare Physician Fee Schedule [109]. Where feasible,

[34] The Technical Agency for Hospital Information (ATIH) is a French public administrative establishment under the supervision of the ministries that publishes the National Cost Study (Étude Nationale des Coûts, ENC or NCS) and the Unit Cost Lists (RTC) [105]. The NCC is France's official hospital cost database and provides production costs for hospital stays. NCS involves a voluntary sample of institutions. All hospital resources excluded from the base tariff in the NCS – including separately funded drugs/devices, ICU supplements, patient co-payments, and private clinic surcharges – must be individually valued and added to the total cost.

[35] HPGs group clinically similar cases with comparable resource used for hospital costing.

[36] The SMC bases its costing on two top-down macro-costing approaches: the NHS NCC and the PSSRU method that provides unit costs for health and social care services [106].

[37] Public Health Scotland's Cost Book is the comprehensive source for Scottish health service costs, used for benchmarking and capturing ~95% of costs across all settings (hospital inpatient and outpatient care, primary and family health, and community sectors) delivered by the 14 territorial NHS Boards (regional healthcare organisations) and national centres. The Cost Book's R100T datasheet [107] is an essential source of national unit cost data, providing per diem costs (national average cost per attendance for day patients), costs for inpatient activity (e.g., cost per case, cost of inpatient surgery, intensive care), costs for long-stay inpatient activity (cost per week), costs for day cases (cost per day case) and day patients (cost per attendance), outpatient and A&E attendances (cost per attendance), diagnostic services (e.g., cost per CT scan, cost per MRI scan), community services (e.g., district nursing, midwifery, and dentistry, all reported as cost per head of population), support services (e.g., catering cost per inpatient week, cleaning cost per square metre). This publication supersedes all previous data from the now-retired Information Services Division (ISD), whose website has been retired and whose functions have been incorporated into Public Health Scotland [108].

bottom-up micro-costing is recommended to capture not only health care utilisation, but also the key elements of the disease process.

allgemein: pragmatischer Methodenmix zur Annäherung an Opportunitätskosten

In summary, while the pursuit of opportunity cost via a pragmatic mix of costing methods is a universal standard, the specific weighting of these methods and their implementation reflect national priorities, from the Netherlands' precision-focused micro-costing standard to the reimbursement-driven macro-costing models of the USA.

Table 4-5 summarises the primary costing approach in each country and its main use case. Section 4.5 Costing Process Step III: Valuation of Resources and Costing Domains elaborates in detail on valuation of each costing domain.

Table 4-5: Overview of the primary costing approaches in each country

Country	Primary costing approach	Key Characteristics, purpose & exceptions
Australia [31, 32]	Top-down macro-costing	■ Preferred for hospital services using the National Hospital Cost Data Collection (NHCDC)[38] to calculate AR-DRG-based unit costs. ■ Bottom-up micro-costing for specific items using the Medical Benefit Scheme (MBS)[39] and Pharmaceutical Benefit scheme (PBS).
Belgium [33, 34]	Top-down macro-costing	■ Primary approach to calculate per diem and unit costs in combination with RIZIV-INAMI reimbursement tariffs ■ Bottom micro-costing for specific items.
Canada [35-37]	Pragmatic Hybrid	■ Flexible, "fit for purpose" approach aligned with analysis perspective. ■ Combination of top-down macro-costing & bottom-up micro-costing.
Denmark [38-41]	Top-down macro-costing	■ Primary approach for calculating DMC unit costs and DRG/DAGS[40]-based unit costs.
England & Wales [42]	Top-down macro-costing	■ Preferred approach for calculating unit costs in the NCC complemented by the Personal Social Services Research Unit (PSSRU) method.
France [43]	Top-down macro-costing	■ Used for HPG-based unit costs. ■ Bottom-up macro-costing to update unit costs and tariffs.
Germany [44]	Pragmatic Hybrid	■ Approach depends on data availability and required precision. ■ Combination of top-down macro-costing, bottom-up micro-costing & top-down micro-costing.
New Zealand [45, 46]	Top-down macro-costing	■ Preferred approach for calculating (average) unit costs (e.g., DRG-based, unit costs in the costing manual) in combination with national tariffs.

[38] The National Hospital Cost Data Collection is aggregate hospital data to calculate average (unit) costs [110].

[39] The Medical Benefits Scheme (MBS) provides standard unit costs (schedule fees) for HEE in PBAC submissions, representing the government subsidy for outpatient services (not the provider's actual cost) [111]. It excludes inpatient hospital services unit costs, which are covered in the National Hospital Cost Data Collection (NHCDC). The Pharmaceutical Benefits Scheme (PBS) Therapeutic Relativity Sheet aligns prices for therapeutically equivalent medicines to ensure cost neutrality. It identifies special pricing arrangements (e.g., confidential discounts) and applies to PBS-listed drugs with comparable clinical effects [112].

[40] The Danish Ambulatory Grouping System (DAGS) is the outpatient equivalent to the DRG system. In 2018, the DRG system merged DRG and DAGS rates into a unified grouping logic, applying identical classification for inpatient/outpatient and primary/assistance activities. Rehabilitation and psychotherapeutic tariffs are also included [113].

Norway [47]	Top-down macro-costing	■ Preferred approach for the NoMA unit costs adjusted by DRG-weighting.
Scotland [48]	Top-down macro-costing	■ Used for (average) unit costs using data from the NHS Cost Book and the PSSRU method. ■ Bottom-up resource identification for specific care and disease pathways.
Netherlands [49, 50]	Bottom-up micro-costing	■ Clear and strong preference for bottom-up micro-costing as the gold standard for published and calculating new unit cost.
USA [51, 52]	Top-down macro-costing	■ Preferred approach for DRG-based and Medicare Fee Schedule-based unit costs.

AR-DRG…Australian Diagnostic Related Groups, DAGS…Danish Ambulatory Grouping System, DMC…Danish Medicines Council, DRG…Diagnostic Related Groups, MBS…Medical Benefit Scheme, NCC…National Cost Collection, NHCDC…National Hospital Cost Data Collection, NHS…National Health Service, NoMA…Norwegian Medical Products Agency, PBS…Pharmaceutical Benefit Scheme, PSSRU…Personal Social Services Research Unit, RIZIV-INAMI… National Institute for Health and Disability Insurance

4.3.2 Identification of Resources and Costs

General Principles

Ressourcenidentifikation:

Kostenkategorien: nationale Prioritäten & Perspektive bestimmen Inklusion/Exklusion

A complete understanding of a country's costing methodology and the variation across countries requires an understanding of the specific reference case and the explicit guidance for handling resources and costs outside the reference case (e.g., in a supplementary analysis or excluded entirely[41]). Included and excluded cost categories reflect national priorities, partially shaped by the selected analytical perspective, ranging from a narrow healthcare budget focus to a comprehensive societal valuation.

Fokus auf inkrementelle Kosten – nur relevante Differenzen

A universal principle across all twelve countries is the use of an incremental cost focus within HEE. This means that the identification of resources centres on items that differ between the new intervention and its comparator(s), with a common recommendation to omit resources whose costs are trivial or offset each other [31-42, 45-47] (Australia, Belgium, Canada, Denmark, England & Wales, New Zealand, Norway). This pragmatic approach ensures the analysis captures only material cost differences relevant to the decision[42].

[41] The specification of cost types is usually part of the identification step in the costing process.

[42] Resources excluded in each specific costing domain are described below in the Section 4.5 Costing Process Step III: Valuation of Resources and Costing Domains in each specific costing domain. Furthermore, the explicit omission of these resources should only be conducted in HEE not in BIA, which guide financial planning of decision-makers.

Relationship of cost types and the analytical perspective in the reference case

Common features

Perspektive: Mehrheit Gesundheitssektor-Perspektive: inkludiert nur direkte med. Kosten – primär budgetrelevant.

The most common framework for the reference case analysis is the healthcare system perspective, which typically includes only direct healthcare costs borne by the public payer or insurance system. Countries adhering to this perspective include:

- Australia [31, 32]: Direct healthcare resources from a healthcare system perspective.
- Belgium [33, 34]: Direct healthcare resources from a healthcare system perspective.
- Canada [35-37]: All relevant direct resources from the publicly funded healthcare payer perspective.
- England & Wales [42]: All resources and costs relating to the NHS and PSS resources.
- New Zealand [45, 46]: All resources and costs from the healthcare system perspective.
- Scotland [48]: All resources and costs from a healthcare system and PSS perspective.
- USA [51, 52]: All relevant resources from the healthcare system perspective.

This collective emphasis ensures the primary analysis is directly relevant to the healthcare budget-holding entity.

Specific Perspective Aspects

spezifische Aspekte hinsichtlich der Perspektive:

Despite the commonalities, several countries have distinct approaches to resource identification. The minority of countries mandating a broader societal or quasi-societal perspective for the reference case follows a broader inclusion of costs by including direct non-healthcare or indirect costs. These are mostly borne by patients and their families as a direct result of the illness or treatment (e.g., travel expenses, patient and caregiver travel and treatment time, and the value of informal care):

- The Netherlands [49, 50] have the most inclusive mandate, requiring all costs within healthcare (also during life years gained), patient and family costs, as well as costs in other sectors such as educational and criminal justice sector. — NLD: umfassend gesellschaftlich
- Norway [47] explicitly includes patients and their caregivers use of time during patient treatment and transport costs, distinguishing who bears the cost. — NOR: Pat.-/Caregiver-Zeit & Transportkosten
- France [43] uniquely focuses on the total direct cost of an intervention, based on the intervention's production costs from a societal perspective[43]. — FRA: Gesamtkosten aus Produktionsperspektive
- Denmark [38-41] specifies a limited societal perspective, suggesting an intermediate position with inclusion of direct cost only. — DNK: begrenzt gesellschaftlich

[43] The societal perspective in France is limited to healthcare, domestic sphere/informal care, and the medico-social sphere (e.g., personal care services). A supplemental analysis may include direct costs from other sectors.

- Germany's guideline [44] is distinct from both narrow payer and full societal perspectives as it defines the SHI-insured community perspective. This perspective requires the inclusion of both reimbursable and non-reimbursable costs.

GKV-Perspektive – erstattete & nicht-erstattete Koste

Out-of-Pocket Payments, Co-Payments and the Perspective

The treatment of patient OOP payments and co-payments reveals largely an alignment with the chosen analytical perspective. In guidelines advocating a healthcare system perspective, these payments are typically excluded from the reference case or should be reported separately or in some cases, no clear information is available. However, this observation is rather a tendency not a rule.

OOP & Zuzahlungen: Tendenz, keine feste Regel.

Countries promoting a societal perspective, like the Netherlands [49, 50], Denmark, France [43], explicitly recommend including them. The French guidelines state that an inclusion in the reference case is consistent with France's societal perspective, which aims to account for the total direct cost of an intervention, including the portion borne directly by the patient. In Denmark, OOP inclusion is also recommended. However, these patient-paid costs are explicitly excluded from the BIA for the healthcare regions, as that analysis only considers costs to the healthcare system. Norway [47] offers a unique insight, noting that OOP payments are disregarded as they are already factored into the DRG weighting system.

OOP-Inklusion in NL, DNK, FRAU

NOR: OOP bereits in DRG-Gewichten

Conversely, Germany, New Zealand, and the USA, all three recommending a healthcare perspective, recommend the explicit inclusion. Co-payments by patients for drugs, medical remedies, aids, and outpatient visits in Germany need to be included in the reference case [44]. The goal is to capture all direct medical costs, regardless of whether the immediate payer is the healthcare insurance provider or the patient, providing a comprehensive view of the financial impact on the insured community.

OOP-Inklusion auch in GER, NZL, USA → Versichertengemeinschaft

In New Zealand [45, 46], direct patient healthcare costs such as GP co-payments are included in the reference case. This aligns with New Zealand's healthcare system perspective that seeks to capture the total cost to the government and the patient for the healthcare provided, ensuring that the full economic cost of a drug or service is reflected, not just the portion subsidized by the state.

NZL: Gesamtkosten Staat + Pat.

The US guideline [51, 52] recommends the inclusion of medical costs paid by patients OOP in its definition of direct healthcare costs for the reference case. While the US uses a healthcare system perspective, it is defined broadly to include all medical expenditures, including direct payments from patients, reflecting a comprehensive payer perspective that encompasses multiple funding sources.

USA: alle medizinischen Ausgaben

Belgium [33, 34] and Canada [35-37] (for its reference case) explicitly state that these costs are excluded. The remaining countries (Australia [31, 32], England & Wales [42], Scotland [48]) do not mention them for inclusion in their healthcare system-focused perspectives, which implicitly implies exclusion.

Exklusion: BEL, CAN (explizit), AUS, E&W, SCT (implizit)

The Perspective and Indirect Costs

indirekte Kosten (Produktivitätskosten) meist exkludiert

A further distinction arises with the inclusion of indirect costs (productivity costs), which is the most divisive element. Most guidelines exclude these from the reference case, but notable exceptions exist. The Netherlands [93, 94] includes a comprehensive assessment of productivity losses from both paid and unpaid work. Germany [57, 58] includes productivity losses from work incapacity, though it explicitly excludes those from premature death if mortality is counted as a benefit in the cost-effectiveness analysis.

Ausnahmen: NLD (bezahlte & unbezahlte Arbeit), GER (Arbeitsunfähigkeit)

In contrast, the USA [95, 96], while including a very wide range of direct medical costs (including unrelated future costs), does not explicitly include productivity costs in the reference case.

Länderspezifika:

Beyond the broad categorisations (direct healthcare, direct non-healthcare, indirect costs), several countries provide specific aspects that refine their costing approach:

- The Netherlands [93, 94] has the most comprehensive reference case, explicitly including costs outside the healthcare system (e.g., municipalities, education, volunteers) and all costs incurred during life years gained.

NLD: sektorübergreifend (Kommune, Bildung, Ehrenamt)

- Germany [57, 58] within the SHI perspective, includes patient co-payments for drugs and outpatient visits, ensuring capture of all direct medical expenditures regardless of immediate payer.

GER: OOP in GKV-Perspektive

- Scotland [92] provides specific guidance on capital and training costs, requiring that capital be annuitised and staff costs must include training and education, reflecting a long-term, fully-loaded NHS costing approach.

SCT: Kapitalkosten annuisiert, Personal inkl. Ausbildung (Vollkosten)

- France [15] uniquely includes costs for care provided by informal caregivers and end-of-life care within direct healthcare costs, highlighting a focus on the entire patient pathway.

FRA: informelle Pflege & Palliativ als direkte med. Kosten

Cost Types in Detail

Umgang mit exkludierten Kosten:

Given that the assignment of cost types to a specific perspective is often ambiguous in practice, perspective-independent analysis is required. This analysis must examine both the cost types included in the reference case and the handling of those excluded from it.

For costs excluded from the reference case, guidelines typically take on of the two approaches:

- Supplementary analysis: Non-reference case costs are calculated and presented separately from the base case, allowing decision-makers to view the full societal picture without altering the standardised result.

Zusatzsanalyse: Gesellschaftsperspektive

- Complete exclusion: Some costs, particularly productivity losses, are deemed outside the scope of the analysis entirely.

vollständiger Ausschluss: Produktivität bleibt unberücksichtigt.

Direct Healthcare Costs

direkte med. Kosten: 12 von 12 Länder; umfasst:

This category is the core of every reference case. All twelve countries include comprehensive direct healthcare costs in their reference case, typically covering:

- Intervention costs: Acquisition costs of pharmaceuticals, medical devices, and technologies.

spezifische Interventionskosten

- Healthcare utilisation: Costs associated with hospital admissions (inpatient and outpatient), inpatient and outpatient physician consultations, diagnostic tests, and emergency department visits.
- Treatment pathway: Costs related to the management of the condition, including treatment of adverse events, follow-up monitoring, reinterventions, and complications.

Gesundheitsleistungen (stationär, ambulant)

Behandlungspfad (Nebenwirkungen, Follow-up, Reinterventionen)

This common core ensures that all evaluations at least capture the immediate medical resources consumed along the treatment pathway. For example, Belgium [33, 34] explicitly lists costs from preparatory examinations to long-term consequences (e.g., reinterventions), while New Zealand [45, 46] details everything from community pharmaceutical spending to GP visits.

Direct Non-Healthcare Costs

direkte nicht-med. Kosten:

The most frequent extension beyond the cost core is the inclusion of direct non-healthcare costs. This category captures mainly tangible expenses borne by patients and families as a direct consequence of illness or treatment, but outside of formal healthcare budgets. The inclusion of these costs signals a broader analytical perspective.

Inklusion in DNK, FRA, GER, NZL, NDL

Direct non-healthcare costs are included in the reference case by Denmark [38-41], France [43], Germany [44], Norway [47], and the Netherlands [49, 50].

Komponenten:

Typical components of direct non-healthcare cost included in the guidelines are:

- Patient and caregiver time: Time spent on treatment-related activities (e.g., attending appointments including travel time, providing care at home). Norway [47] includes patient's and their caregiver's use of time during patient treatment, and France [43] uniquely specifies care provided by informal caregivers.
- Transportation costs[44]: Travel expenses to and from healthcare providers are explicitly referenced in guidelines from Denmark [38-41], France [43], Norway [47], the Netherlands [49, 50], and Germany [44].

Pat.-/Caregiver-Zeit (Behandlung, Anreise, informelle Pflege) &...

...Transportkosten

Informelle Pflege & Pat.-Zeit:

meist exkludiert oder bedingt

Bedingt: E&W (nur wenn NHS/PSS-Ersatz), Schottland (bei signifikanter Kostenbeeinflussung)

Zusatzanalyse: BEL, FRA (optional)

Half of the guidelines exclude informal care or patient and caregiver time from the reference case, confining it to conditional inclusion, supplementary analysis or excluding it entirely, in line with a healthcare system or payer perspective. According to the English and Welsh guideline [42], informal care should only be included if it substitutes for NHS and PSS services. This is a pragmatic, budget-focused approach that only values care that directly offsets formal healthcare costs. In Scotland [48], informal care should only be included if the main treatment costs are significantly affected by informal care costs and suggests using English cost data sources like the PSSRU [106]. Belgium [33, 34] and France [43] offer the option to include informal care in a supplementary analysis without providing an explicit method. The remainder of the guidelines provide no specific information on the inclusion or recommend the exclusion of informal care or patient and caregiver time, suggesting it is not a standard component of their evaluation framework. These include Australia [31, 32], New Zealand [45, 46], and the USA [51, 52].

[44] Ambulance services are typically classified as direct healthcare costs. However, due to overlap with general transport costs, they are subsumed under the valuation domain Transport, Travel Expenses, and Ambulance.

The Belgian guidelines [33, 34] explicitly state that transport and travel costs must be excluded from the reference case, though they may be reported separately if significant. The guidelines from Scotland [48] specify that patient travel costs fall outside the NHS perspective. England & Wales [42], New Zealand [45, 46], and the USA [95, 96] provide no specific guidance for including and valuing these costs, suggesting they are not a standard component of the reference case.

unterschiedlicher Umgang mit Transportkosten (e.g., BEL: exludiert, SCT: außerhalb NHS-Perspektive)

A complete picture of which services are ultimately included and how they are valued can be found in the Section 4.5 Costing Process Step III: Valuation of Resources and Costing Domains.

Indirect Costs (Productivity Costs)

Several guidelines consistently distinguish productivity costs (capturing lost labour market production) from patient and caregiver time including informal care and traveling time[45] (capturing the total opportunity cost of time spent on health-related activities, including travel). This distinction is crucial for transparency, preventing double-counting, and addressing different policy questions.

Produktivitätskosten:

klare Trennung von Pat.-/ Caregiver-Zeit → vermeidet Doppelzählung

As mentioned, two guidelines include productivity costs in the reference case. The Netherlands [49, 50] includes comprehensive productivity losses (absenteeism, presenteeism) for both paid and unpaid work. Germany [44] pursues a partial approach by including productivity losses from work incapacity but excludes losses from premature death in the reference case.

...nur in NDL & GER berücksichtigt

Most guidelines exclude productivity costs from the reference case. Among those that exclude productivity costs, two patterns appear:

- Full exclusion of productivity costs.
- Consideration of productivity costs permitted only in a supplementary analysis.

According to the Australian guideline [31, 32], the inclusion of indirect costs and presentation in a supplementary analysis requires a detailed economic rationale, noting that many productivity impacts may be absorbed by the wider economy (e.g., short-term absences are made up on return, long-term absences replaced by a worker who would otherwise be unemployed). Canada [35-37] and Belgium [33, 34] mandate that if productivity costs are considered in a supplementary analysis, they must use the FCA (which accounts for market adjustments to absenteeism) to maintain a tight focus on the healthcare budget.

Zusatzanalyse:

AUS: nur mit Begrüdung

CAN, BEL: falls Inklusion dann FCA

The guidelines from Denmark [38-41], England & Wales [42], New Zealand [45, 46], and Norway [47] indicate that productivity costs should not be included at all.

[45] Some single guidelines or also parts of the health economic literature equate productivity cost and “lost” time due to caregiving activities.

Cross-Sectoral, Transfer Payments and Intangible Costs

Sektorübergreifende Kosten in NLD (Bildung, Justiz)

Reporting on the handling of cross-sectoral impacts, transfer payments, and intangible costs differs across national guidelines. For cross-sector costs, the inclusion depends on the chosen perspective, and most countries mandate a health system perspective. With this perspective, costs from other sectors are excluded a priori. While the Dutch guidelines [49, 50] state that cost from the education and justice system sector are included due to the societal perspective, the US guidelines [51, 52] state that costs in social services, education, and housing are excluded from the reference case, but may be included in a supplementary societal perspective analysis. The English & Welsh guidelines [42] state that cross-sector costs are in principle not included at all but may be considered if agreed in advance and reported separately from the reference case [42]. Similarly, Scotland mandates that any non-NHS and non-PSS costs must be reported separately from NHS costs.

USA: Exklusion, aber ergänzend möglich

E&W & SCT: nur nach Absprache & separat

keine finanziellen Transfers berücksichtigt

Financial transfers between segments of society (e.g., unemployment benefits, disability pensions) are rarely addressed, where mentioned, they are explicitly excluded from cost calculations, e.g., Belgium [33, 34], Canada [35-37], Denmark [38-41], Germany [44], and New Zealand [45, 46]. The rationale, as stated by Denmark, is that they are transfers, not socio-economic costs.

intangible Kosten

The German guidelines explicitly exclude intangible costs, such as those for pain and suffering, arguing they are captured via QALYs [44]. Belgium [33, 34] and Germany [44] also specify that leisure time effects should be excluded, with Germany allowing for their consideration only in sensitivity analysis.

Future Cost and Future Cost Changes

Zukünftige Kosten: krankheits-/ interventionsbezogene Kosten inkludiert, aber auch Uneinigkeit

Treatment of future cost (changes) varies substantially across guidelines and costing manuals. While there is consensus that future costs directly linked to the disease or intervention should be included, jurisdictions diverge on whether to include future healthcare costs unrelated to the condition being treated, but which are incurred during life-years gained. This creates a fundamental split between the full-life costing approach and related-costs-only perspective.

interventionsbezogene Zukunftskosten: Follow-up, Monitoring, Komplikationen, Reinterventionen

All guidelines require the modelling of long-term treatment pathways, including follow-up medications, monitoring, management of complications, and re-interventions. For instance, Canada [35-37] explicitly states that future costs should be included for clinical or care pathways with resource-intensive health states. Germany [44] recommends the inclusion of costs of medical care directly related to the gained life years from the intervention (e.g., follow-up drugs and check-ups). England & Wales [42] mandates the inclusion of survival-related costs in the reference case.

Kostenänderungen: Zurückhaltung bei spekulativen Preisänderungen im Basis-Fall.

Furthermore, several guidelines share a pragmatic and evidence-based approach to predicting cost changes. There is a common reluctance to build speculative future price reductions that translate into cost changes into the base case without strong evidence. Belgium [33, 34] and France [43] both argue that potential future price reductions (e.g., from generics) should only be included if evidence exists, otherwise, they should be tested in sensitivity analysis. Scotland [48] requires that predictions of future practice must be justified using multiple sources, emphasising the need for robustness in forecasting.

Kosten gewonnener Lebensjahre

The primary divergence lies in the handling of unrelated future healthcare costs, leading to two distinct approaches:

- The inclusionist view, mainly recommended by countries with a societal perspective in HEE: This group of countries argue that all future healthcare consumption, because of extended life, is a real cost to the system and must be accounted for to avoid biasing interventions that extend life. The Netherlands [49, 50] is the most explicit, stating that for lifelong time horizons, all future costs must be included, including those incurred during years of life gained. The USA [51, 52] similarly recommends inclusion of future related and unrelated health care costs of survival.

Inklusion: NDL, USA – alle Kosten in gewonnenen Lebensjahren als realer Systemaufwand

- The exclusionist view, mainly recommended by countries with a healthcare system perspective: This group argues that including unrelated medical costs unfairly penalises life-extending therapies and that the analysis should be focused on the costs and consequences of the specific decision at hand. Norway [47] excludes costs of patients' future use of public services and unrelated health service costs. New Zealand [45, 46] states that indirect future health care costs (e.g., from living longer) should not be included.

Exklusion: NOR, NZL – Fokus auf entscheidungsspezifische Kosten

DNK mit Mittelweg

Denmark [38-41] takes a middle-ground, limiting inclusion to treatment-related expenses only. Canada [35-37] offers a unique perspective by suggesting analysts consider dynamic relationships between resource volumes and unit costs, such as savings from lowered doses, moving beyond a simple static costing model.

Table 4-6 provides an overview of the scope of the reference case costs and handling of excluded costs for each country.

Table 4-6: Overview of the scope of reference case costs and handling of excluded costs for each country

Country	Direct healthcare costs	Direct non-healthcare costs	Indirect costs (Productivity)	Unrelated future medical/ disease costs	Key nuances in reference case	Handling of excluded costs (Non-reference case)
Australia [31, 32]	✓	X	X	X	Strictly limited to health system resources.	Productivity: Supplementary analysis only.
Belgium [33, 34]	✓	X	X	X	Focuses on costs/savings within and across health conditions.	All excluded costs: Only included in supplementary analysis.
Canada [35-37]	✓	X	X	X	Defined by the boundary of publicly funded services.	Productivity: Supplementary analysis only, using the FCA.
Denmark [38-41]	✓	✓ (Time, Travel)	X	X	A limited societal perspective; includes patient/relative time and travel.	Productivity/Future Costs: Never included, but if calculated, must be presented separately.
England & Wales [42]	✓	X	X	X	Includes NHS/PSS costs like staff training and infrastructure.	Productivity: Should not be included at all. Other sectors: May be considered following prior agreement but should be reported separately.
France [43]	✓	✓ (Medico-social)	X	X	Explicitly includes informal caregiving and end-of-life care.	Productivity: Excluded, only considered in a supplementary analysis.
Germany [44]	✓	✓ (Travel, Time)	✓ (Limited)	X	Includes patient co-payments and productivity losses from death are excluded.	Intangible costs, such as pain and suffering, are excluded, only included in sensitivity analysis.
New Zealand [45, 46]	✓	X	X	X	Includes direct patient payments (co-payments) within the health system perspective.	All non-healthcare costs and productivity are considered at all.
Norway [47]	✓	✓ (Transport, Time)	X	X	Includes costs paid by the patient and caregiver and their time.	Productivity not included at all.
Scotland [48]	✓	X	X	X	Includes annuitised capital costs and staff training.	Non-NHS/PSS costs: If considered, must be reported separately from NHS costs.
Netherlands [49, 50]	✓	✓ (All)	✓ (Comprehensive)	✓	The most comprehensive: approach includes costs in other sectors (e.g., education, criminal justice etc.).	All major costs included in reference case.
USA [51, 52]	✓	X	X	✓	Uses a healthcare system perspective but includes unrelated future medical costs.	Patient time, transportation, other sectors: Included in a detailed supplemental societal perspective analysis.

✓ *…Yes*

X *…No*

FCA…Friction Cost Approach, NHS…National Health Service, PSS…Personal Social Services

4.4 Costing Process Step II: Resource Use Measurement

4.4.1 Cost Units

Ressourcenmessung

Kosteneinheiten: Messung in natürlichen Einheiten (klinisch/administrativ)

Guidelines and costing manuals broadly agree on the principle of using natural units to quantify resource consumption, ensuring that resource use is measured in tangible, clinical, or administrative terms before monetary valuation. The descriptive analysis of these units reveals a taxonomy that reflects both clinical reality and the structure of national healthcare systems, with granular variation across resource types and their application.

Taxonomie:

A high degree of harmonisation exists for several core healthcare services, though with subtle distinctions in their definition and taxonomy:

- Non-inpatient healthcare services: The unit cost per consultation or visit is universal for outpatient and community-based care [31, 33-52]. However, some guidelines add specificity, e.g., England & Wales [42] distinguish costs per general practitioner (GP) consultation and community nurse visit, or cost per minute (via PSSRU), while the Netherlands [49, 50] and Canada [35-37] further use cost per session or per hour, indicating time-based granularity for certain professional (outpatient and healthcare) services.

  ambulant: Konsultation/Besuch (universal), teils Zeitbasis (NLD, CAN: pro Stunde/Sitzung; E&W: pro Minute)

- Pharmaceuticals: While most countries use simple units like cost per unit (tablet, vial) or per pack, a significant number also advocate for standardised consumption measures. The Defined Daily Dose (DDD) is explicitly recommended in Canada, England & Wales, Germany, Scotland, and the Netherlands [35-37, 42, 44, 48-50] to support consistent cost comparisons across different drug regimens. Many guidelines link drug costs to the patient journey, using units such as cost per treatment cycle (Belgium, France) [33, 34, 43], cost per patient per year (France) [43], or cost per defined course of therapy (Canada) [35-37], demonstrating a focus on the total therapeutic cost rather than just the acquisition price of a single unit.

  Arzneimittel: pro Tablette/Ampulle/Packung, teils ergänzt um DDD teils Zyklus (B, F), oder Pat. oder Jahr

- Hospital services: There is a clear international preference for DRG-based or episode-based costing. Most countries rely on national DRGs or case-mix systems as their reference unit, such as DRGs (Australia, Germany, Norway, USA), Healthcare Resource Groups[46] (HRGs) (England & Wales, New Zealand), Case-Mix Groups (CMGs) (Canada), or HPGs (France) [35-37, 42-47, 51, 52]. The Scottish [48] and Belgian [33, 34] guideline recommend the use of per diem cost units. The guidance from England & Wales [42] provides an explicit hierarchy: If HRG is inappropriate, analysts should use cost per bed-day, per outpatient attendance, or per staff hour. This acknowledges that a single unit cannot capture all hospital activities and offers a pragmatic set of alternatives. Alongside these complex units, simpler measures like cost per procedure (France, Germany, Netherlands) [43, 44, 49, 50] or cost per admission (Denmark) [38-41] remain common, often for straightforward interventions.

  Krankenhaus: DRG-basiert (internationaler Standard)

  Alternativen: per Diem, Prozedur, Aufnahme

  E&W: Hierarchie (HRG → Bettentag → Ambulanz → Personalstunde)

[46] The HRG approach uses standardised procedure categories similar to DRGs and bundles costs per admission or per procedure.

Beyond these commonalities, the guidelines differ particularly in the treatment of medical devices, care outside hospitals beyond "standard" healthcare services such as home or residential care, and the scope of included costs:

Länderspezifika:

- Medical devices: A key divergence is whether device costs are itemised or absorbed within broader tariffs or unit costs. Some countries, like Belgium, France, the Netherlands, and New Zealand, explicitly require a cost per device unit, often with instructions to amortise the cost over its expected use [33, 34, 43, 45, 46, 49, 50]. In contrast, others, such as Denmark, Germany, and Scotland, note that these costs are typically included in hospital care costs [38-41, 44, 48] or DRG/HRG tariffs, implying they are not separately identified in the reference case. This represents a fundamental difference in costing philosophy between itemisation and bundled payment.

  Medizinprodukte: itemisiert vs. in DRG integriert

- Other healthcare-related services (e.g., residential care, home care, and home nursing): Variation appears primarily in the categorisation of non-acute care. Several guidelines and costing manuals provide detailed units that reflect a continuum of care outside the hospital. Australia [31, 32] specifies units for per Aged Care Funding Instrument[47] (ACFI) service categories: cost per day for residential care, cost per day for home care, and cost per hour for home nursing. The Canadian guideline [35-37] recommends a DRG cost unit equivalent for residential care services in the form of cost per day using Resource Utilisation Groups (RUG-III) with each group having a Case Mix Index (CMI)[48]. Distinct cost units for other services can also be observed in the guidelines of England & Wales [42], France [43], and the Netherlands [49, 50], highlighting a formal recognition of the cost structures within long-term and social care systems, which are often overlooked in less detailed frameworks.

  Langzeitpflege & soziale Dienste: detaillierte Einheiten

- Transport, travel, and productivity: The inclusion of specific units for transport and productivity reflects differing analytical perspectives. Units like cost per trip (ambulance) in Australia [31, 32] and cost per journey in Germany [44] capture direct medical transport. Furthermore, the inclusion of productivity costs in some reference cases requires the use of time-based units. Canada, Germany, and Norway explicitly mention units like cost per hour of lost time or cost per day of absence [35-37, 44, 47], which aligns with their adoption of a broader societal or quasi-societal perspective for the reference case by including non-healthcare or indirect costs in their scope.

  Transport: pro Fahrt/Reise

  Produktivität: zeitbasierte Einheiten bei gesellschaftlicher Perspektive.

Table 4-7 provides a summary of the cost units used for the main four costing domains[49].

[47] The Aged Care Funding Instrument (ACFI) determines daily subsidies for aged care by assessing dependency in three domains: Activities of daily living (ADL), behaviour, and complex care needs, with tiered funding (low/medium/high). Rates are updated quarterly. The basic daily fee is paid by the care recipient [114].

[48] CMI reflects the within group complexity or resource use and RUG reflects between-group complexity or resource use.

[49] Only the cost units for the four "main" cost domains ("Healthcare Services", "Pharmaceuticals", "Medical Devices", and "Hospital Services") are listed here. The cost units for the other costing domains (productivity, residential care etc.) are mainly time-based.

Table 4-7: Overview of the main cost units for the main costing domains in each country

Country	Non-inpatient healthcare services	Hospital services (inpatient)	Pharmaceuticals	Medical devices
Australia [31, 32]	Cost per service / consultation	Cost per episode of care (AR-DRG classification)	Quantity dispensed	Not specified
Belgium [33, 34]	Cost per consultation / test / session	Cost per day (Belgian per diem) / stay / procedure	Cost per unit / pack / cycle	Cost per device / procedure
Canada [35-37]	Cost per visit / consultation / hour	Cost per case / per diem (CMG classification)	Cost per unit / DDD / course	Cost per device
Denmark [38-41]	Cost per consultation / visit	Cost per admission / procedure	Cost per unit / vial / patient	Included in hospital costs
England & Wales [42]	Cost per GP consultation / nurse visit / minute	Cost per bed-day / attendance (HRG classification)	Cost per unit / DDD / course	Cost per device / procedure
France [43]	Cost per consultation / procedure	Cost per stay / day (HPG classification)	Cost per unit / cycle / patient-year	Cost per device unit
Germany [44]	Cost per service / consultation	Cost per DRG case / stay	Cost per DDD / package	Included in DRG costs
New Zealand [45, 46]	Cost per visit / day care	Cost per case (HRG classification)	Cost per patient (dose/duration)	Cost per device unit / use
Norway [47]	Cost per contact / consultation / unit	Cost per DRG case / bed-day	Cost per package	Cost per medical device
Scotland [48]	Cost per visit / consultation	Cost per bed-day (Scottish per diem) / procedure	Cost per unit / DDD / course	Included in NHS Scotland tariffs
Netherlands [49, 50]	Cost per consultation / session / hour	Cost per procedure / day / visit	Cost per DDD / package / issue	Cost per item
USA [51, 52]	Cost per physician visit	Cost per DRG case	Cost per mg / dose	No specific guidance

AR-DRG…Australian Diagnostic Related Groups, CMG…Case Mix Groups, DDD…Defined Daily Dose, DRG…Diagnosis Related Group, GP…General Practitioner, HPG…Homogeneous Patient Groups, HRG…Healthcare Resource Group, NHS…National Health Services

4.4.2 Data Sources

General Data Sources

Datenquellen: gemeinsame Hierarchien & nationale Spezifika für lokale Relevanz

The guidelines for measuring resources share common hierarchies of data sources and evidence, while also detailing specific national data sources and processes to ensure local relevance. They also show nuanced positions on the use of real-world evidence, formalised costing and specifically measurement hierarchies, and the role of expert opinion.

Präferenz klinischer Effekt: RCTs, SR, Meta-Analysen als Goldstandard

There is universal consensus on the preferred sources for clinical effectiveness: RCTs, SRs, and meta-analyses are consistently positioned as the gold standard across all twelve countries [31, 33-52]. This reflects a shared commitment to high quality comparative clinical evidence.

Regarding resource-use measurement, RCTs and observational studies primarily inform clinical effectiveness but are also used to quantify resource use. However, the identified guidelines acknowledge the different roles of various data types. RCT may capture protocol-driven resource use [35-37] and thus might have limited generalisability to routine care, whereas RWD is explicitly valued for measuring non-protocol resource use and is sourced from a wide array of national administrative databases, hospital records, and claims data. Although all 12 countries refer to and consult these types of sources for identifying resources, eight explicitly report them (Belgium, Canada, England & Wales, France, Germany, Scotland, Netherlands, USA) [33-37, 42-44, 48-52].

RCTs oft protokollgetrieben → begrenzte Generalisierbarkeit

RWD explizit für nicht-protokollierte Ressourcennutzung

Finally, clinical and treatment guidelines are frequently cited as key sources for defining standard practice and resource use, notably in Canada [35-37], New Zealand [45, 46], the Netherlands [49, 50], and the USA [51, 52].

weitere Quellen: Klinische Leitlinien & Behandlungspfade

Expert Opinion

The identified countries also strongly agree on the role of supplementary data sources. Expert opinion is generally accepted only to complement, validate primary data, or fill gaps where empirical data is lacking. The Australian [31, 32], Belgian [33, 34], Canadian [35], English & Welsh [42], French [43], and Scottish [48] guidelines specify a set of conditions for expert panel use in HEE, including for resource measurement and for cost data (e.g., expert selection criteria or the detailed method to collect the expert opinions). Scotland's [48] guideline is particularly detailed regarding resource use data. Expert opinion in Scotland is an acceptable data source when study data is lacking, provided the expert selection process is transparent, and estimates are tested in sensitivity analyses.

Expert:innenmeinung: nur ergänzend bei fehlenden Daten

manche Leitlinien mit spezifischen Anforderungen (Auswahlkriterien, Erhebungsmethoden, Sensitivitätsanalyse)

Country-Specific Data, Local Applicability and Foreign Data

Most guidelines stress local applicability and the careful validation of foreign data. This is explicitly required in Australia [31, 32], Belgium [33, 34], Denmark [38-41], New Zealand [45, 46], Norway [47], and Scotland [48], which mandate validating international data and adapting it to national clinical practice and cost structures. For example, the Scottish guideline mandates similar stringency to foreign resource use data as for the use of expert opinion. Foreign data may be used but should be avoided if possible or at least validated for the Scottish setting [48].

lokale Anwendbarkeit & internationale Daten:

Validierung & Anpassung an nationale Praxis

Beyond the common hierarchy, several countries have distinctive, formalised processes and preferred data repositories to adapt to healthcare system specifications:

Länderspezifika

- The Netherlands [49, 50] has one of the most explicit description for costing sources including the identification of resources, which is also reflected by the costing manual [50]. The costing manual states that "*although clinical studies, patient self-reporting and healthcare registries are the most valuable sources for the collection of volume data, it is impossible to distinguish any clear hierarchy between these sources. Information from national registries, literature, consultations with experts and the Diagnosis Treatment Combination (DTC) information system are less preferable. The most suitable volume measurement method needs to be assessed for each study*". The

NDL: mehrere Quellen und Tools zur Messung der Produktivität

costing manual is also unique in specifying standardised tools[50] (iVICQ, iCARE, iPCO) for measuring informal care time and productivity losses, supporting methodological consistency in complex domains.

- Belgium also provides an extensive list of national databases for the measurement (and valuation) of resources including the information on data access: The Technical Unit for the processing of data relating to hospitals (TCT) collects linked hospital clinical and billing data (restricted access) [118], InterMutualist Agency (IMA–AIM) collects individual reimbursement data (e.g., billing data) for insured patients (restricted access) [119], Minimum Hospital Data (MZG-RHM) by the Federal Public Service (FPS) Health, Food Chain Safety and Environment collects hospital discharge data (restricted access) [120]. BEL: umfangreiche nationale Datenbanken
- Germany [44] mandates a highly systematic and obligatory exploratory information retrieval from a predefined and diverse list of national sources, including Dynamed [121], UpToDate [122], guideline databases (e.g., AWMF [123]), Robert Koch Institute [124], Federal Statistical Office (Destatis) [125], Federal Employment Agency (Bundesagentur für Arbeit – BA) [126], Allgemeine Ortskrankenkasse[51] Research Institute (WIdO) [127], regional registries, laws, regulations, directives. This prescriptive process for identifying resources for cost estimation and BIA leaves little room for ad-hoc source selection. GER: systematische Recherche in vordefinierten Quellen (Dynamed, Destatis, WIdO, AWMF etc.)
- England & Wales [42] and Scotland [48] provide extensive, practical lists of specific national data repositories (e.g., Hospital Episode Statistics, National Services Scotland etc.). This effectively creates a default "toolkit" for analysts, ensuring consistency by using nationally recognised data assets. In England & Wales [42], non-randomised evidence and data may be used to provide estimates of resource use for populating economic models: Hospital data such as Hospital Episode Statistics [128], Primary care data through the PSSRU [106], Prescribing data (e.g., systemic anti-cancer therapy (SACT) activity [129]), UK Health Security Agency (UKHSA) [130], Healthcare Quality Improvement Partnership (HQIP) [131], Hospital pharmacy audit index [132] (provided by IQVIA, an American private company focused on health information technology), industry or company submissions, and Local Government Association (LGA). E&W: "Toolkit" nationaler Datenassets (e.g., PSSRU) für Konsistenz
- France [43] emphasises its national data infrastructure: The Medical IT system (PMSI) for Medicine, Surgery, Obstetrics and Odontology (MSO), Hospitalisation at Home (HAH), Follow-up Care and Rehabilitation (FCR) services database, and the annual statistics of healthcare institutions (SAE) as key sources, particularly relevant for "disease follow-up and end-of-life care", indicating a tailored use of data sources for specific disease stages. FRA: spezifische medizinische IT-Systeme
- Canada [35-37] descriptively lists a wider range of source types, including product monographs and the World Health Organisation CAN: breite Quellentypen (Monographien, WHO-DDD

[50] Informal care time is measured by the Institute for Medical Technology Assessment (iMTA) Valuation of Informal Care Questionnaire (iVICQ) [115] or the informal CARE effect (iCARE) tool [116]. Productivity losses are measured via the iMTA Productivity Cost Questionnaire (iPCQ) [117].

[51] The Allgemeine Ortskasse (AOK) is a local SHI fund.

(WHO) Defined Daily Dose (DDD)[52] [133] to define units of measurement.

- In the USA [51, 52], resource data and economic impacts of the interventions are identified through the scoping process and drawn from the identified evidence: Mainly the evidence from the SR including clinical trials but also standard treatment guidelines. Additional economic data should preferentially come from publicly available sources (e.g., Healthcare Cost and Utilization Project – HCUP, publications using commercial claims data, Medicare [109], and the RED BOOK®[53]).

USA: öffentlich zugängliche Quellen bevorzugt (HCUP, Medicare, RED BOOK®

Further domain-specific data sources are listed in the Section 4.5 Costing Process Step III: Valuation of Resources and Costing Domains.

4.5 Costing Process Step III: Valuation of Resources and Costing Domains

4.5.1 General Principles of Resource Valuation

Commonalities

Bewertung

Valuing resource use in all 12 countries follows similar recommendations on standardisation, transparency, and relevance to the national healthcare system. The primary goal is to approximate opportunity costs and reflect real-world costs faced by the decision-making authority (government, health policymaker, [health] insurance provider). Predominantly, this means calculating and using official (national) unit costs, complemented by official (national) tariffs, fee lists, or prices. Although the hierarchy of data source for valuation slightly differs for specific costing domains, countries consistently mandate the use of or provide specific, often government-published or legislated approaches in costing manuals, catalogues and schedules:

Ziel: Annäherung an Opportunitätskosten

primäre Quellen: nationale Unit Costs, Tarife, Gebührenordnungen

- Australia [31, 32] directs analysts to the Manual of Resource Items, the MBS, and the PBS[39].

AUS: MBS, PBS, Manual of Resource Items

- England & Wales [42] and Scotland [48] prioritise the NHS National Cost Collection (NCC) [1], NHS Payment Scheme, and PSSRU[36] [106] unit costs. The Netherlands [49, 50] have a formal, hierarchical list of sources, with national unit costs based on costing studies at the top.

E&W: NHS NCC, PSSRU

[52] The Defined Daily Dose (DDD) is a statistical measure of drug consumption, defined by the WHO as the assumed average maintenance daily dose for a drug's main use in adults. It is used to standardise comparisons of drug usage [133].

[53] The RED BOOK® is a comprehensive resource providing current drug pricing, product descriptions, and manufacturer information for prescription and over-the-counter pharmaceuticals to simplify drug identification and comparison.

- New Zealand [45, 46], Canada [35-37], Denmark [38-41], Norway [47], and France [43] all reference primary national catalogues (analogous to the Netherlands, Scotland, and England & Wales), federal fees and prices or HTA body-provided cost manuals. For example, the different Canadian ministries of health (e.g., British Columbia MSP Payment Schedule [134], Alberta Health: Medical price list [135]) provide federal fees and prices listed in schedules, formularies or provincial lists of covered medications[54] to value services and goods.

NZL, CAN, DNK, NOR, FRA: nationale Kataloge, Gebührenordnungen, Formulare

NDL: nationale Unit Costs (aus Studien) bevorzugt

- Belgium [33, 34] and Denmark [38-41] prefer market prices for marketed products (i.e. unit cost should reflect market prices). For non-commercial healthcare services, standard (national) reimbursement tariffs by the RIZIV-INAMI [136] and costs published in the DMC unit cost catalogue[55] [41], similar to countries using national catalogues, should be used for valuation.

BEL, DNK: Marktpreise (Produkte), RIZIV/DMC-Katalog (Leistungen)

Valuation of Out-of-Pocket and Co-payments

Bewertung OOP: keine einheitliche Praxis

The inclusion of OOP payments and co-payments in the reference case is predominantly aligned with the chosen analytical perspective. Therefore, valuation aspects of OOP or co-payments are mostly reported only in guidelines mandating a broader perspective (see Out-of-Pocket Payments, Co-Payments and the Perspective). If reported, the valuation is quite diverse.

GER: gesetzlich fixierte Zuzahlungsbeträge pro Rezept/KH-Tag – keine Marktpreisschätzung

The German guideline [44] does not specify a single published list but refers to the standard co-payment rates mandated by German social law (Sozialgesetzbuch V). These are fixed amounts per prescription or per day of hospital stay. The analysis uses these legally defined co-payment amounts, not estimated or averaged market prices.

NZL: Vollkosten inkl. Zuzahlung

Arznei: Listenpreis + fixer Zuzahlungsbetrag

Konsultation: Ø Pat.-Zuzahlung + staatl. Erstattung

New Zealand [45, 46] mandates valuation at full cost including wastage, regardless of patient co-payment. The valuation is integrated into the primary pricing sources for pharmaceuticals and healthcare services. For pharmaceuticals, the full cost is derived from the net price negotiated with the supplier in the Pharmaceutical Schedule plus the patient co-payment. The co-payment is a fixed, known amount within the New Zealand healthcare system. For GP visits, the cost calculation explicitly includes the patient co-payment added to the government-reimbursed amount. The guideline specifies that this is calculated as the sum of the average cost to the patient plus the amount reimbursed by the government per visit.

NDL: www.medicijnkosten.nl

The Netherlands [49, 50] costing manual provides some guidance and sources for the valuation of personal contributions of medicines (www.medicijnkosten.nl by the ZIN) and other services such as transportation.

[54] Provincial and territorial ministries publish annual fee schedules and drug formularies (e.g., Ontario Drug Benefit Formulary, Saskatchewan Drug Formulary, or British Columbia PharmaCare), though some require direct access. Alternative Payment Plans (ARPs) for delivering specific program services supplement fee-for-service models but often require institutional access for details [37].

[55] The DMC catalogue provides unit costs and methods for valuing unit costs including references to sources (only available in Danish). The catalogue guides all costing and resource domains, though alternatives may be used with justification [41].

The French guideline [43] states that when using tariffs for valuation of any healthcare-related service, any patient surcharges need to be included. The National Health Insurance statistics data (SNIIRAM) [137], the National Health Data System (SNDS)[56], and the Official Gazette (Journal officiel) [139] publish the official tariffs. Discrepancies between these tariffs or fees and actual patient payments or market prices must be documented and analysed in a sensitivity analysis.

FRA: Pat.-Zuzahlungen bei Tarifen inkludieren

Marktpreisabweichungen dokumentieren & analysieren

In Denmark [38-41], the full dispensing price should be used for medicines that patients pay for themselves at the pharmacy. If the medicine receives a public subsidy, the patient's OOP portion must be included in the analysis of costs per patient.

DNK: Apotheken-Abgabepreis (Vollkosten)

Norway's guideline [47] offers a unique insight, noting that OOP payments are already implicitly factored into the DRG weighting system and national unit price.

NOR: bereits implizit in DRG & Unit Costs

The US guideline is not that explicit regarding the valuation and only recommends the use of publicly available cost data, which includes patient OOP payments.

USA: öffentliche Daten

Inflation and Foreign Cost Data Adjustment

Another near-universal principle is inflation adjustment: Costs must be expressed in current/base-year currency. While most use a general Consumer Price Index (CPI), some specify sector-relevant indices (e.g., the USA's [51, 52] Personal Consumption Expenditures for Healthcare (PCE-H) index and Scotland's [48] United Kingdom (UK) health service price index). Foreign cost data use exhibits slight variation: Canada, New Zealand, and Scotland do not recommend using such data; Germany, Norway, and the Netherlands provide no specific guidance on foreign data use and cost adjustment. The remaining six guidelines recommend approaches ranging from using (market) exchange rates, purchasing power parity (PPP) adjustment, to a two-step approach (Belgium). Table 4-8 gives an overview of the different approaches.

Inflationsanpassung: universell – Kosten in aktueller Landeswährung. (VPI oder teils sektorspezifisch)

Auslandsdaten: heterogene Wechselkurse

Table 4-8: Inflation and foreign cost data adjustment in each country

Country	Inflation adjustment	Foreign cost adjustment
Australia [31, 32]	Australian price index (AIHW)	Only recommended if an adequate exchange rate is used.
Belgium [33, 34]	HICP	CPI adjustment of foreign data → OECD PPP adjustment → Validation
Canada [35-37]	CPI	Foreign cost data use is not recommended (only in sensitivity analysis).
Denmark [38-41]	CPI	PPP adjustment & use of central bank exchange rates.
England & Wales [42]	NHS/PSS inflation indices	Use of current exchange rates.
France [43]	CPI	PPP adjustment
Germany [44]	CPI	Not reported
New Zealand [45, 46]	2% for pharmaceuticals	Foreign cost data use is not recommended.
Norway [47]	CPI	Not reported
Scotland [48]	UK Health Service Index	Foreign cost data use is not recommended (if used, validation for Scottish setting necessary)
Netherlands [49, 50]	CPI	Not reported
USA [51, 52]	PCE-H Index	Use of current exchange rates

[56] The National Health Data System (SNDS) makes it possible to link health insurance data (SNIIRAM database), hospital data (PMSI database), the medical causes of death, disability-related data, a sample of data from complementary health insurance organisations [138].

AIHW…Australian institute of health and welfare, CPI…Consumer price index, UK…United Kingdom, OECD…Organisation for economic cooperation and development, PCE-H Personal consumption expenditures for healthcare, PPP…Purchasing power parity

Specific Valuation Aspects

Länderspezifika

Beyond these commonalities, several countries provide highly specific and unique methodological guidance:

NDL: strenge Bewertungshierarchie

The Netherlands [49, 50] stands out for its explicit and strict hierarchy of costing sources, rigorously prioritising reference prices[57] or unit costs, preferably from bottom-up micro-costing studies, over negotiated tariffs (DTC), underscoring its commitment to reflecting economic resource consumption. The valuation hierarchy, listed in descending order of preference is:

- Costing studies by the Ministry of Health, Welfare and Sport (VWS), published cost price studies, or already established reference prices and unit costs based on costing studies in the CM.
- Financial registries and National databases, e.g., Zorgcijfersdatabank, Medicines and medical devices Information Project-databank (GIP)[58], Statistical Netherlands (CVB), etc.
- Dutch Healthcare Authority (NZa) tariffs and maximum medicine reimbursement rates[59] provided by ZIN.
- Market prices.
- DTC tariffs (least preferred, as they are negotiated prices, not necessarily reflecting economic costs).

Kostenstudien als bevorzugte Quelle

The costing approaches in the Netherlands are mainly used for the hospital context, but the Dutch National Health Care Institute (ZIN) states that the methodology can be largely used for costing studies at healthcare providers other than in hospital. Some domains or components are not equally relevant in every healthcare context outside the hospital[60] (e.g., accommodation-related costs are less relevant in primary care but relevant in nursing homes).

[57] The reference prices for many types of healthcare services are listed in the costing manual and should be preferably used. In some instances, reference prices are not available, or they are too inaccurate for the evaluation in question. In that case new independent costing studies are required. If reference prices and costing studies are not available, the specified costing approaches in combination with other evaluation units, such as financial healthcare registries, NZa rates, market prices, or DTC rates, can be used.

[58] The Zorgcijfersdatabank serves as the primary repository for statistical data on the Dutch healthcare sector, encompassing metrics like healthcare expenditure and patient volumes. The GIP-databank (Medicines and Medical Devices Information Project) catalogues information pertaining to medicines and medical devices eligible for reimbursement through the Dutch healthcare system.

[59] The NZa establishes maximum rates for various types of care, including GP and dental services. A key issue is that these rates do not directly reflect a procedure's actual cost, as they also serve macro-budgeting and income policy purposes. The primary source for determining cost of medicines is www.medicijnkosten.nl by the ZIN.

[60] Deviations from the standard costing approach for hospital services are described in the Sections 4.5.2 to 4.5.11 on the valuation of each costing domain.

The English & Welsh guideline [42] recommends in case that costs or prices vary (e.g., regional differences), analysis of both highest and lowest costs or prices using the midpoint in sensitivity analyses should be conducted. Scotland [48] provides particularly detailed guidance on staff and capital costing, requiring that staff costs include all employer costs and that capital costs be annuitised, reflecting a long-term opportunity cost perspective that is more comprehensive than in many other guidelines.

E&W: bei Kosten-/ Preisvariation → Sensitivitätsanalysen

SCT: annuisierte Kapitalkosten

Belgium [33, 34] and France [43] have the most detailed processes for integrating foreign costs. Belgium mandates a dual adjustment for inflation (using the foreign Harmonised Index of Consumer Prices – HICP[61]) and currency conversion (using OECD PPP data), followed by validation for the Belgian context. Furthermore, if the intervention has no official market price, the Belgian guidelines recommend estimating costs using manufacturer input, treatment protocols, similar interventions, literature, or administrative data.

BEL & FRA detailierte Prozess bei Auslandsdaten & Inflationsbereinigung

VAT handling is explicitly addressed by England & Wales [42], Denmark [38-41] and Scotland [48], which consistently require its exclusion from the HEE but inclusion in the BIA, a crucial distinction for financial planning.

E&W, DNK, SCT: VAT-Inklusion in BIA

4.5.2 Non-Inpatient Healthcare Services

The valuation of non-inpatient healthcare services (primary, specialist, diagnostic, and partially community care) demonstrates a universal reliance on standardised national payment systems, as outlined in the Section 4.5.1 General Principles of Resource Valuation. However, a closer look indicates slight variations in how these systems are structured and applied, from the direct use of listed fees to derivations of true economic (unit) cost, reflecting fundamental differences in how healthcare is financed and organised.

nicht-stationäre Leistungen: nationale Vergütungssysteme

Most countries (nine of the 12) recommend applying the the costing methodology for (outpatient) healthcare services to outpatient services delivered in a hospital. This reflects the view that the costing of all outpatient healthcare services should be based on their intended designation as outpatient care, irrespective of the setting in which they are delivered. Denmark, France, and the Netherlands are exceptions, as they apply a unified hospital costing approach that also covers hospital outpatient services (see Hospital Services).

9/12 Länder: Methodik für ambulante Leistungen = KH-Ambulanz-Leistungen

Common Features Across Countries

Sources

A dominant theme across all countries is the use of official national fee schedules, tariffs, aggregate cost databases or (unit) cost collections to value physician and diagnostic services. This measure should ensure consistency and alignment with real-world financing. Sources fall into three types:

Bewertungsquellen ambulante Leistungen:

- Nationally mandated tariffs: Key sources include the RIZIV-INAMI reimbursement scheme in Belgium [33, 34], the EBM catalogue in Germany [44], the Poliklinikkforskriften (Outpatient regulations) [47] and the Norwegian Health Economics Administration (HELFO) [140] in

Nationale Tarifwerke: BEL, GER, NDL, FRAU, DNK

[61] The HICP (Harmonised Index of Consumer Prices) is a standardised EU measure for comparing inflation across member states, with methodology and expenditure rules defined by European regulations.

Norway. In France, laboratory, medical imaging procedures and technical medical procedures should be valued based on tariffs[62] from the National Health Insurance and the national laboratory table (TNB). In the Danish primary sector, the basis for unit costs should be agreements on consultation or procedure tariffs by the Danish Regions and the relevant negotiating partner PLO-RLTN collective agreement for GPs [141], FAS-RLTN[63] collective agreement for 15 specialties [142].

- Centralised cost databases or cost collections for unit costs and aggregate costs to calculate unit costs: Key sources include the NCC, NHS Payment Scheme, PSSRU data in England & Wales [42], the NoMA Unit Cost database in Norway [47], ZIN's reference prices in the Netherlands [49, 50], the DMC unit cost catalogue [41] in Denmark, the NHS Cost Book in Scotland [48] including UK-wide data such as the NCC, and the National Health Insurance statistics data (SNIIRAM) [137], the National Health Data System (SNDS), and Open Data platforms (Open Damir, Open Bio) [143] in France.

zentrale Kostendatenbanken: E&W, NOR, NDL, DNK, FRA

- Benefits and fee schedules: Key sources include the Medicare Benefits Schedule (MBS) in Australia [31, 32] and the Physician Fee Schedule (PFS) [109] in the USA [51, 52]. Canada [35-37] is the prime example, explicitly listing provincial fee schedules from Alberta (Price list), British Columbia (Payment schedules), Manitoba (Physician manual), and Ontario (Laboratory services) for physician and diagnostic services [134, 135, 144, 145]).

Gebührenordnungen: AUS, USA, CAN

Some countries give explicit guidance on what to exclude from the valuation of healthcare services – just as important as what to include. Beyond the universal practice in HEE of omitting resources that do not differ between the new intervention and its comparator(s), Belgium [33, 34] explicitly mandates excluding additional charges (e.g., private room supplements), so the reference case reflects standard care. Denmark [38-41] similarly recommends excluding basic GP tariffs (non-service-specific), focusing the analysis on resources specifically consumed due to the intervention.

Fokus auf interventionsbedingte Ressourcen

Specific Aspects

Beyond the common use of standardised unit costs or tariffs, several countries provide unique methodological approaches that reflect the characteristics of their healthcare systems:

Länderspezifika

[62] Medical imaging procedures (e.g., CT, MRI) should be valued using official classification of procedure codes (CCAM) tariffs plus a national average for technical fees (reference activity). For high-cost procedures involving radiopharmaceuticals (e.g., PET scans), the drug cost is included in or added to the tariff. Contrast agents are valued at retail price, with discounts tested in sensitivity analyses.

[63] PLO = Praksislægernes Organisation (General Practitioners' Organization/Denmark's union for self-employed GPs). RLTN = Regionernes Lønnings- og Takstnævn (Regional Wage and Tariff Board/Sets fees and salaries for public healthcare providers). FAS = Foreningen af Speciallæger (Association of Specialist Physicians/Denmark's union for medical specialists). RLTN = Regionernes Lønnings- og Takstnævn (Regional Wage and Tariff Board/Government body setting fees for public healthcare).

NZL: pro-Kopf-basierte Kostenerfassung für Primärversorgung

Radiologie/Labor: Ø-Preise großer Anbieter (exkl. Steuern)

New Zealand [45, 46] provides detailed guidance on capitation-based costing in primary care. The cost of a GP visit equals the patient co-payment plus a calculated government portion (annual capitation fee divided by the estimated number of visits). This untangles the population-based pre-payment (capitation) into a usable fee-for-service equivalent unit cost, a method not explicitly described in any other guideline. The cost for services like magnetic resonance imaging (MRI), computed tomography (CT), and X-rays[64] should be based on an average of prices from major radiology providers, excluding taxes. Cost per pathology tests should be based on an average of prices from major laboratory providers, also excluding taxes. Hospital outpatient costs[65] (e.g., outpatient clinic visits, ED, day procedures) are valued using Outpatient Purchase Unit[66] (PU) prices, which bundle all associated costs like staff time, administration, and overheads into a single price for the event. Community service[67] costs (e.g., residential care, ambulances) are valued using specific per-event or per-day rates from provider schedules or national averages, sometimes also utilising PU prices.

NOR: NoMA-Unit-osts-Datenbank

Norway [47] applies a distinctive multiplier to official GP and specialist consultation tariffs – NoMA unit cost are doubled to account for public subsidies and overheads – making listed tariffs reflect the full economic cost. Furthermore, the Norwegian Medical Association (NMA) for primary care and outpatient services also provides an overview of relevant tariffs, patient contributions, and subsidies for healthcare services, but the NoMA unit cost database should be the basis for valuation [47].

CAN:

Canada [35-37] provides details on valuing specific (outpatient) services, within a "fit for purpose" (hybrid) approach (i.e. micro-costing within a macro-costing framework). It recommends:

- Time-based valuation for radiology, accounting for equipment, technicians, and physicians. — Zeitbasiert (Radiologie),
- A critical distinction between the costs of single tests versus panel-testing in laboratories. — Einzel- vs. Panel-Tests (Labor)
- The use of manufacturer or purchaser quotes for medical devices, acknowledging the difference between list prices and confidential negotiated discounts. — Hersteller/Einkäufer-Angebote (Geräte)

[64] Imaging services in the (inpatient) hospital setting are already included in the DRG price in New Zealand.

[65] Outpatient visits and services in New Zealand comprise of outpatient clinic visits, specialist consultations and minor operations, emergency department visits, dental care (in most cases the full cost is to the patient from age 18 years), blood transfusions performed as an outpatient or elective day case, travel and accommodation reimbursed through the Ministry of Health National, Travel Assistance Scheme, outpatient education and case management sessions.

[66] Outpatient purchasing units (PUs) are a standardised system for measuring, quantifying, and valuing healthcare services, including those delivered in outpatient settings, to support consistent costing, funding, and service planning across the health system [146].

[67] Community services include palliative care, residential care (rest home, dementia care, and hospital care for the health of older, people), home nursing, personal care and home help, prenatal and postnatal care, disability support services funded by the Ministry of Health, ambulance services.

Germany [44] maintains its clear distinction between reimbursable and non-reimbursable costs, requiring that patient co-payments for outpatient visits be included in the valuation. This aligns with its SHI-insured community perspective, which aims to capture all direct medical costs, regardless of who immediately pays.

Unterscheidung erstattungs- und nichterstattungsfähige Leistungen

The Netherlands [49, 50] and France [43] both emphasise the use of actual cost data over tariffs. The Netherlands does this through its strict hierarchy of sources, while France prioritises average costs from National Health Insurance statistics data (SNIIRAM) [137] to reflect real resource consumption rather than just negotiated prices for non-inpatient healthcare services. In the Netherlands, if no reference prices (unit costs) for primary and paramedical healthcare are available, the services should be valued by a top-down macro-costing approach using national aggregate expenditure and production data.

NLD: Top-down-Makro-Costing bei fehlenden Unit Costs (Referenzpreise)

The English & Welsh guidelines [42] highlight a common feature of many costing manuals: Healthcare services are less standardised than hospital inpatient unit costs and often rely on local or regional data.

ambulante Leistungen oft weniger standardisiert → regionale/lokale Daten.

4.5.3 Pharmaceuticals

Common Features Across Countries

The valuation of pharmaceuticals aims to reflect the actual cost to the health system, but with national variations in data sources, handling of (confidential) discounts, and the granularity of cost components.

Pharmazeutika: nationale Unterschiede bei Datenquellen, Umgang mit Rabatten & Detailtiefe

Sources

Most countries mandate the use of list prices or market prices for novel pharmaceuticals, non-reimbursed prescription drugs and over-the-counter (OTC) medicines and official public databases for reimbursed pharmaceuticals as primary data sources.

Quellen:

- Official national formularies, tariffs, negotiated or list/retail/market prices: This is the most common approach. Examples include the Pharmaceutical Benefits Scheme (PBS) or the A-Z medicine list [147] in Australia [31, 32], the RIZIV-INAMI Farmanet database [148] or the Belgian Centre for Pharmacotherapeutic Information (BCFI) drug prices for non-reimbursed and OTC drugs [149] in Belgium [33, 34], the NHS Drugs Tariff [150] in England & Wales [42], the British National Formulary (BNF) [151] in Scotland [48], and provincial formularies or retail prices of OTC drugs in Canada [35-37].

  nationale Tarife & Formelsammlungen

- HTA agency databases: Some countries, such as Denmark [38-41], Norway [47] and the Netherlands, provide dedicated databases through their HTA bodies (Medicinpriser.dk [152], NoMA website [153]). The Netherlands recommends the use of the Market Regulation Act (WMG) medicines cost prices for prescription-only

  HTA-Datenbanken

medicines or the sales price for OTC medicines [45, 46] (via www.medicijnkosten.nl[68] [156]).

- Commercial and regulatory databases: Germany [44] references the information service provider for pharmaceuticals (Informationsstelle für Arzneispezialitäten – IFA) [157] database and the LAUER-TAXE®, while the USA [51, 52] uses a combination of public sources (Medicare ASP files [158]) and commercial data (RED BOOK® [159], SSR Health [160]).

kommerzielle/ regulatorische Datenbanken

Specific Aspects

Länderpsezifika:

Although some guidelines (e.g., Belgium, Denmark, and France) state that market prices should be used for the valuation of pharmaceuticals, especially novel drugs, a dominant, cross-national theme is the rejection of the simple ex-factory price. Most guidelines favour a more comprehensive "cost of therapy", recognising that a drug's resource impact includes wastage, administration, and dispensing. However, this common notion is also subject to varying interpretations, leading to distinct national valuation approaches, with only partial overlaps across countries, especially for novel or non-reimbursed pharmaceuticals.

"Therapiekosten"-Ansatz inkl. Verschwendung, Applikation, Abgabe

unterschiedlich umgesetzt (besonders bei nicht-erstatteten Arzneimitteln)

Consideration of the Pharmaceutical Market

Marktberücksichtigung

Some guidelines recommend the active use of valuation methods to account for market competition and incentivise cost-effective behaviour:

BEL: Vergleich gegen günstigstes Generikum (Wettbewerb).

Belgium [33, 34] instructs to use the lowest-priced generic for treatment alternatives (even if rarely used) to drive prices down. It ensures that the economic case for a new drug is judged against the most competitive alternative rather than higher-priced brands that may still have a market share ("generic competition").

FRA: Marktpreis oder volumen-gewichteter Ø-Verkaufspreis bei nicht-erstatteten Arzneien

The French guideline [43] requires non-reimbursed pharmaceuticals to be valued at the market price or at a volume-weighted average selling price if the drug is sold at a free market price exceeding the reimbursement tariff. Volume-weighted averages according to market shares should reflect actual purchasing patterns. If the tariff of reimbursed pharmaceuticals and medical device does not cover all funder expenses, then the actual price paid or a weighted average price is used.

NZL: Modellierung künftiger Generika-Eintritte & Preisverfall (z. B. -70%).

New Zealand's guideline [45, 46] requires anticipated price modelling by modelling future generic entry and price reductions (e.g., 70% reduction) for drugs nearing patent expiry. It prevents paying a premium for a new drug when its cost-advantage is known to be temporary, effectively shortening the window of cost-effectiveness for branded products.

USA: differenziert nach Status (Marke/ Generikum), Applikation, Preistransparenz

The US [51, 52] guideline recommends varying the valuation method based on a drug's status (branded/generic), administration route, and price transparency. This approach acts as a complex regulatory mechanism. By using the

[68] WMG costs (available at www.medicijnkosten.nl) = Purchase/List price provided by ZIN + Costs pharmaceutical care or Issuing costs. Further aggregated data available in the Medicines and medical devices Information Project (GIP) database [154] (www.gipdatabank.nl; freely accessible) and at the Foundation for Pharmaceutical Statistics (SFK; www.sfk.nl; freely accessible) [155].

average sales price (ASP) plus markup for administered drugs, this approach directly links reimbursement to real-market prices.

Discounts, Rebates, and Confidential Prices

Rabatte & vertrauliche Preisinformationen: unterschiedliche Ansätze

Some guidelines define strategies for incorporating (confidential) price information in the reference case, e.g., from patient access schemes (PAS) or managed entry agreements (MEA)[69] (e.g., in Belgium). Across guidelines three main approaches appear:

- Net price valuation: New Zealand's guideline [45, 46] recommends the use of directly negotiated net prices in the reference case available from the Pharmaceutic Schedule [161]. The US guideline [51, 52] states that an estimated net price should be used for branded drugs by applying average discounts from commercial sources (e.g., SSR Health) to the list price. The Netherlands generally recommends to use the WMG cost, which is based on the list price and only to use discounts, if data from healthcare insurers is available [49, 50]. — Nettopreisbewertung: NZL, USA, NDL
- List versus confidential price valuation: In England & Wales [42], the list price is used in the public analysis, whereas the discounted PAS price should be applied in the confidential decision-making process. Scotland [48] mandates that both the list price and the PAS price must be presented in the analysis. — Listenpreis vs. Vertraulich: E&W, SCT
- Scenario/Sensitivity analysis for discounts: In Belgium [33, 34] and Canada [35-37], the reference case mandates the use of the list price and the impact of confidential discounts is explored in an additional analysis. — Szenario-/ Sensitivität:sanalyse BEL, CAN

Valuation Distinction by Treatment Setting

Setting-spezifische Bewertung: 5 Länder differenzieren nach Applikationsort

Five countries (Australia, Canada, Denmark, England & Wales, the Netherlands) explicitly differentiate their valuation methods based on where the pharmaceutical is administered. According to the identified guidelines, the differentiated consideration of the setting should ensure the understanding that the same drug imposes different cost structures depending on where and how it is delivered.

- Australia's [31] guidelines are the most explicit example, with distinct, legislated pricing formulas for community pharmacy, private hospitals, public hospitals, and six different highly-specialised drug programs (S100)[70]. — AUS: verschiedene Preisformeln (e.g., öffentliche vs. private KH)
- Under Canada's non-universal valuation approach [35-37], different cost components – community dispensing fees and markups, and drug administration costs – must be sourced from their respective provincial fee schedules. — CAN: Provinztarife für Abgabe, Aufschlag, Applikation
- England & Wales [42] formally separate pricing by using the NHS Drugs Tariff for primary care and the NCC for secondary care. — E&W: Primär- vs. Sekundärversorgung)
- The Netherlands [49, 50] acknowledges a potential distinction by noting that inpatient medicines may require a top-down adjustment for — NDL: stationärer vs. WMG-Preis

[69] Patient Access Schemes or Managed Entry Agreements are utilised in several countries; however, only the Belgian (MEA), Scottish (PAS), and English & Welsh (PAS) guidelines explicitly report on them in the context of valuation.

[70] A complete overview of the formulas can be found in the separate Appendix.

discounts. If no information is available, then also the WMG cost price is used [156].

- The Danish guideline [38-41] requires the inclusion of additional investment costs for implementation (e.g., specialised database setup) in the pharmacy purchasing price. These investment costs can vary by setting, ensuring hidden implementation costs are captured.

DNK: zusätzliche Interventionskosten im Apothekeneinkaufspreis

Inclusion of Drug Wastage

Four countries (Australia [31, 32], Belgium [33, 34], New Zealand [45, 46], Norway [47]) mandate inclusion of wastage (e.g., broken packs, unused vials, non-compliance) in the reference case. In practice, this is handled by valuation at full cost including wastage or valuation per full package to account for wastage. The rationale is to avoid artificially improving cost-effectiveness of a drug by ignoring the real-world packaging and administration inefficiencies, and to base comparisons on actual resources consumed.

Verschwendung inkludiert in AUS, BEL, NZL, NOR

Bewertung: Vollkosten inkl. Verschwendung oder pro Packung

Comprehensive Therapy Costing

Guidelines in five countries (Australia [31, 32], Canada [35-37], Norway [47], New Zealand [45, 46], USA [51, 52]) explicitly move beyond the drug price to include additional costs like dispensing, administration, and markups. The Norwegian guideline [47], despite specifying the preference for a top-down macro-costing approach, employs micro-costing for infusion fees of pharmaceuticals. This detailed approach, which includes labour costs from pharmacy, disposable equipment, and additives plus a 25% overhead, ensures full reimbursement for the infrastructure of complex therapies.

Therapie-Vollkosten: Arzneipreis + Abgabe + Applikation + Aufschläge (5 Länder)

As noted, the US guideline [51, 52] recommends the inclusion of markups on the ASP for provider-administered drugs to cover administration costs and the Canadian guideline refers to drug administration costs from provincial fee schedules.

Aufschlag für applikationsnahe Kosten (USA, CAN)

Table 4-9 provides an overview of valuation characteristics for pharmaceuticals in each country including sources, used values, and country-specific characteristics.

Table 4-9: Overview valuation characteristics for pharmaceuticals in each country

Country	Source(s)	Prices used and handling of (confidential) discounts	Additional cost considered	Further country-specific aspects and implications
Australia [31, 32]	■ PBS Schedule [162] ■ A-Z medicine list [147]	■ List price in reference case ■ Discount use unclear/not specified	Yes (Dispensing fees, mark-ups, wastage)	Setting-specific pricing formulas to ensure precise costing across the entire health system.
Belgium [33, 34]	■ RIZIV-INAMI (Farmanet) [148]	■ List price in reference case ■ Discounts in scenario/sensitivity analysis	Yes (Wastage)	Generic competition via lowest-price rule and adjustments for real-world compliance enhancing realism.
Canada [35-37]	■ Provincial formularies (Ontario Drug Benefit Formulary [163], Saskatchewan Drug Formulary [164], or British Columbia PharmaCare [165])	■ List price in reference case ■ Discounts in scenario/sensitivity analysis	Yes (Dispensing fees, markups, administration)	Setting-specific pricing approaches to ensure national relevance.
Denmark [38-41]	■ Medicinpriser.dk (DMC) [152] ■ DMC catalogue [41]	■ Pharmacy purchase prices in the reference case ■ Discount use unclear/not specified	Yes (Administration, wastage already in the purchasing price)	Setting-specific pricing by considering additional investment costs.
England & Wales [42]	■ NHS Drugs Tariff [150]	■ List price for reference case "public analysis" ■ PAS price (discount) in confidential committee	Yes (Considered in hospital costs)	Two analyses: Public and confidential committee analysis.
France [43]	■ Official Gazette (Journal official) [139] ■ Price catalogues (official market prices)[71]	■ Market price in reference case ■ Discount use is unclear/not specified	Yes (Dispensing fees, average acquisition costs)	Volume-weighted averages (market shares) to reflect actual purchasing patterns.
Germany [44]	■ IFA [157] ■ LAUER-TAXE® databases [166]	■ List price in reference case ■ Unclear/Not specified	Unclear/Not specified	Relies on regulatory databases and standardised pricing methods to ensure consistency.
New Zealand [45, 46]	■ Pharmaceutical Schedule [161]	■ Net price valuation in reference case ■ Discount use unclear/not specified	Yes (Dispensing, administration, mark-up, wastage[72])	Models future generic entry, protecting long-term system sustainability.
Norway [47]	■ NoMA Website (Pharmacy Retail Price) [153]	■ List price in reference case ■ Discounts in scenario/sensitivity analysis	Yes (Detailed infusion fees with 25% overhead)	Detailed consideration of administration to ensure the valuation of full cost
Scotland [48]	■ BNF [151] ■ MIMS[73] [167]	■ List and PAS price must be used and presented.	Unclear/Not specified	Two analyses: Dual pricing shows the direct impact of the discount.
Netherlands [49, 50]	■ ZIN's www.medicijnkosten.nl (Dutch National Health Care Institute, 2025 #939} ■ ZIN's GIP database [154] ■ Foundation for Pharmaceutical Statistics [155].	■ Usually WMG cost (list price based) in reference case ■ Discount use only if information is available	Yes (Costs calculated via standard formula)	Standardised formula (WMG cost prices) ensures a consistent and efficient derivation of net drug cost.

[71] France provides different sources for measurement and valuation (tariffs and prices) of pharmaceuticals. Each provides specific information on usage, reimbursement, pricing, and volume. National Health Insurance expense data: Open MEDIC (aggregated use), OPEN PHMEV (prescribed products), Retroced_AM (reimbursement bases), BdM_IT (prices); retail (pharmacy) sales/prescription data: ANSM (sales to hospitals/retail), SDM (pharmacy prices), GERS (units sold/sales); and hospital sales/consumption data: Xpr-So-Open-health (real-time dispensing), HOSPI PHARMA-IMS/HOSPIWARD-IMS (intra-hospital dispensing), AFSSAPS Tax (hospital sales).

[72] According to PHARMAC, pharmaceutical administration costs can arise in three settings: hospital inpatient, hospital outpatient, outpatient (home, GP surgery, hospice, or residential care). The calculation of these costs depends on the personnel and structures utilised in each specific setting.

[73] Monthly Index of Medical Specialities (MIMS) is a UK-wide pharmaceutical reference for healthcare professionals providing essential information on medicines for prescribing and clinical decisions.

USA [51, 52]	■ RED BOOK® [159] ■ Medicare ASP Files [158] ■ SSR Health[74] [160]	■ Net price valuation in reference case	Yes (Administration mark-ups)	Complex valuation methodology based on the drug's status (branded/generic), administration route, and price transparency to links reimbursement to market prices.

ASP… Average Sales Price, BNF…British National Formulary, DMC…Danish Medicines Council, IFA… Information service provider for pharmaceuticals/Informationsstelle für Arzneispezialitäten, MIMS… Monthly Index of Medical Specialities, National Health Care Institute, NHS…National Health Service, NoMA… Norwegian Medical Products Agency, PAS…Patient Access Scheme, PBS…Pharmaceutical Benefit Schedule, RIZIV ZIN… National Institute for Health and Disability Insurance

[74] SSR Health provides a net price database of industry data used by academics, brand manufacturers, policymakers etc. and IPD Analytics provides manufacturer-reported sales data and rebate information.

4.5.4 Medical Devices

Common Features Across Countries

Bundled Versus Itemised Valuation

Medizinprodukte (2 Ansätze):

gebündelt (in DRG/Leistung): CAN, DNK, GER (pragmatisch, aber intransparent).

International guidelines reveal a fundamental dichotomy in the valuation approach of medical devices compared to pharmaceuticals, primarily due to their heterogeneity and complex cost structures. Many health systems, including those in Canada [35-37], Denmark [38-41], and Germany [44], treat medical devices as an integral part of a clinical service rather than as a separate commodity. In these countries, the cost of a device is not itemised but is absorbed within broader healthcare service tariffs or unit costs, such as DRG-based costs for hospital cases or fees for specific procedures. This bundled approach is pragmatic and aligns with existing hospital payment mechanisms, but it can obscure the true cost of the device itself and may be insensitive to the economic impact of introducing a new, innovative technology. Section 4.5.5 (Hospital Services (Inpatient)) provides information on the valuation of hospital services including bundled valuation.

itemisiert: BEL, FRA, E&W (NHS Supply Chain), NDL & NOR (Lieferantenlisten), NZL

In contrast, a second group of countries mandates an itemised valuation approach, requiring the device to be costed as a discrete product. This guideline group aims to directly assess the value of the device. Within this group, there is a common reliance on official or health system-specific price sources to ensure consistency and reflect real-world costs. The Belgian guideline [33, 34] makes a reference to the official RIZIV-INAMI database of implants (sIMPL) [168]. France [43] refers to reference prices (tariffs) from official catalogues (tarif forfaitaire de responsabilité – TFR[75]) like the Products and Services Qualifying for Reimbursement (LPPR) catalogue [169]. England & Wales [42] prefers actual procurement costs from the NHS Supply Chain catalogue [170]. The Netherlands [49, 50] and Norway [47] use supplier lists or publicly listed retail prices from their national health authority databases. In New Zealand, PHARMAC provides a comprehensive medical devices list with contracted listing prices, which are used as a starting point for valuation [171].

This shared preference of these six countries for itemised costing using standardised sources provides a consistent benchmark for valuation.

Specific aspects

Länderspezifika

Beyond this division, several countries provide detailed and unique guidance that refines their approach.

NZL: Lebenzyklus-Kosten

New Zealand [45, 46] explicitly acknowledges that device costs extend far beyond the purchase price. Its guideline uniquely mandates a full lifecycle cost analysis, which includes:

[75] The TFR is a reference price set by the French healthcare pricing committee (CEPS) for medical devices, procedures, and other healthcare products, used to determine reimbursement levels. France provides sources for measurement and valuation (tariffs and fees) of medical device resources. Each provides specific information on usage, reimbursement, pricing, and volume. National Health Insurance expense data: List of products and services/LLP (reimbursed amounts and face prices), non-hospital retail sales/prescription data: ANSM (sales to hospitals/retail), SDM (pharmacy prices), hospital sales/consumption data: Xpr-So-Open-health (real-time dispensing).

- One-off costs, such as the negotiated price, disposal of old devices, implementation, and switching costs.
- Fixed costs including additional staff, overheads, and training costs.
- Variable costs for operating, maintenance, repair, and consumables.

NOR: separate Bewertungen von zusätzlichen Leistungen

Norway [47] provides specific guidance on the interaction between devices and other resources, stating that the cost of any pharmaceutical or additional service used with the medical device must be valued and included separately. The Scottish guideline [48] states that devices without the requisite marketing authorisation are excluded from its assessment process. For authorised devices, Scotland [48] proposes a mixed model, where routine devices are absorbed within NHS tariffs, but a device that is specifically required for a new treatment should have its official price itemised in the economic model. The Australian [31, 32] guideline explicitly excludes medical devices from evaluations for its PBS. The US [51, 52] guidelines do not provide device-specific guidance, but the Value Assessment Framework outlines specific considerations for the assessment of non-drug interventions (devices, digital health technologies, diagnostic test, and delivery system innovations) [52].

SCT: Routineprodukte in DRG, neue Geräte itemisiert

AUS: keine Bewertung von Medizinprodukten

USA: Framework für Nicht-Arzneimittel

4.5.5 Hospital Services (Inpatient)

Common Features Across Countries

stationäre KH-Leistungen:

Fallgruppen/DRG-basiert als Primärmethode & per Diem als pragmatische Alternative

The valuation of hospital services demonstrates a high degree of international convergence, with a preference for case-mix or DRG-based systems as the primary method for costing inpatient care. By grouping clinically similar patients with comparable resource use, these systems account for patient complexity and ensure fair comparisons. Alongside this, per diem rates remain a common, pragmatic alternative, particularly for non-acute care or when more granular data is unavailable.

Keine Einheitslösung → Hierarchien & Ausweichoptionen

Generally, the guidelines reveal that no single method fits all scenarios, leading to the establishment of valuation hierarchies and fallback options.

Case-Mix System (DRGs and Equivalents)

Fallgruppen-Systeme: DRG-basiert (oder Äquivalente) in 9 Ländern

A large majority of countries utilise case-mix systems to value hospital episodes. These systems use a standardised national price or cost weight for each patient group, providing a more accurate picture of the cost of an entire episode of care than simple daily rates. Examples include Australia [31, 32] (AR-DRGs), Canada [35-37] (CMGs with Resource Intensity Weights), Denmark [38-41] (DRGs & DAGS), England & Wales [42] (HRGs), France [43] (HPGs), Germany [44] (DRGs), New Zealand [45, 46] (DRGs with Weighted Inlier Equivalent Separations), Norway [47] (DRGs), and the USA [51, 52] (DRGs). In addition, Australia [31, 32] has a highly structured system using Urgency Related Groups[76] (URGs) for emergency department visits and Tier 2 classifications for non-admitted care.

The rationale stated across guidelines for this shared methodology, is its ability to link payment to the patient's condition and treatment intensity. For

[76] The URG system classifies emergency department visits by clinical urgency (Australasian Triage Scale 1-5) and resource use, with costs ranging from ~$ 150 (non-urgent) to ~$ 1,200 (resuscitation). These NHCDC-derived cost weights apply only to non-admitted care; admitted patients use AR-DRG pricing instead.

example, a complex surgical procedure is assigned a higher cost weight than a straightforward medical admission, ensuring the valuation reflects actual clinical activity.

Per Diem and Other Standardised Rates

per Diem: für Bereiche ohne DRG (Psychiatrie, Langzeit, ambulant)

For specific scenarios where case-mix groups are inappropriate or unavailable, most guidelines provide plan B options using standardised daily or per-event rates. This is often the case for long-term care, psychiatric stays, or outpatient visits where the concept of a discrete episode is less defined.

BEL: detaillierte Tagessätze nach Fachbereichen

weitere Länder mit per Diem-Bewertung: CAN, NOR, SCT

The use of per diem rates is explicitly mentioned in Belgium [33, 34], Canada [35-37], Norway [47], and Scotland [48]. Belgium's [33, 34] guideline is particularly detailed, specifying different per diem rates for acute care (A), burns (BRA), geriatrics (G), palliative (PAL), psychiatric (P), and specialised/chronic care (Sp). Per diem costs for salaried personnel, physicians, pharmaceuticals, medical support, overheads, investments should be taken from the RIZIV-INAMI database [136] or calculated according to the Belgian Cost Manual for hospital interventions based on RIZIV-INAMI or other aggregated hospital data[77]. The per diem rates in Belgium only cover basic costs. Additional costs such as intensive care unit (ICU) costs or medications must be added. The default calculation is a simple average (unweighted, all hospitals equal). A weighted average approach is preferred but requires non-public volume data that accounts for case-mix disparities. For emergency care, and partially for hospital outpatient care, countries use per-event costs.

Valuation Hierarchy and Cost Adjustments

klare Bewertungshierarchie: nationale DRG-Datenbanken (Top-down-Makro) für Konsistenz, aber feinkörnigere Methoden bei Bedarf

Countries generally establish a clear hierarchy of preferred data sources, prioritising DRG-based national averages via top-down macro-costing for consistency but allowing for more granular methods when necessary for accuracy.

Most countries designate a central, national database of unit costs or tariffs as the primary source:

- Australia's National Hospital Cost Data Collection (NHCDC) and the associated National Public Sector Cost Weights (NPSCW)[78],
- Denmark's DRG rates [172] (for inpatient care) and DAGS tariffs (for outpatient care) provided by the Danish Health Data Agency [113],
- England & Wales's NCC, and
- France's NCS and the unit cost reference lists (RTC) [105]

are prime examples, designed to reflect average health system costs to ensure all evaluations use a consistent benchmark.

Mikro-Costing bei Heterogenität/ neuen Leistungen

Recognising the limitations of averages, several guidelines explicitly recommend micro-costing for new or heterogenous services. Denmark [38-41] recommends to use a micro-costing approach using the Municipal salary data [173] for staff time (adjusted for holidays, child care, and other breaks) and market prices for equipment, when DRG rates mask heterogeneity. In France [43], if NCS data are unreliable (low sample size, high uncertainty), HRG

[77] TCT hospital clinical and billing data (restricted access) [118], IMA (individual billing data) (restricted access) [119], MZG-RHM hospital (discharge) data (restricted access) [120].

[78] The NPSCW are standardised cost benchmarks used in Australia to cost hospital services for activity-based funding and economic evaluations.

tariffs published in the Official Gazette (Journal official) [139] should be used, and for new or unlisted procedures (e.g., robotic surgery), micro-costing is recommended. The Dutch guidelines [49, 50] recommend a micro-costing approach as the preferred method for high-cost procedures.

Specific Aspects

Länderspezifika

While some valuation principles are shared, several countries provide unique methodological insights that refine the valuation hierarchy.

normalerweise klare Trennung ambulante & stationäre Leistungsbewertung

DNK, FRA, NLD wenden KH-Methodik auch auf ambulante KH-Leistungen

Most guidelines explicitly separate the valuation of inpatient and outpatient care, applying the specific inpatient costing methodology only to services for formally admitted (inpatient) patients. As an exception, the Danish, French, and Dutch guideline also recommend that hospital outpatient services should be costed using the methodology for hospital services. In Denmark, the use of tariffs from the merged DRG/DAGS system, rehabilitation, and psychotherapeutic tariffs provided by the Danish Health Data Agency are recommended to value hospital outpatient services [113]. In France, the valuation of hospital inpatient and hospital outpatient services should be done by using unit costs provided in the NCS, which considers HPGs, and the unit cost reference lists [105]. The Dutch [49, 50] costing hierarchy is specifically intended for the hospital context including hospital outpatient services. The hospital-focused hierarchy prioritises reference prices derived from bottom-up micro-costing studies and the CM for high-cost items, complemented by top-down unit costs (e.g., bed-days) from suggested national sources.

CAN: Hierarchie: Per Diem → CMG → Ø Pat.-Kosten → pat.-basiertes Mikro-Costing

Canada's guideline [35-37] specifies a four-step framework in descending order of preference:

- Per diem: Using average daily rates from budget reports.
- CMG costing (DRG-based): Using national Resource Intensity Weights (RIWs) to reflect clinical complexity and variation in resource intensity across cases compared to per diem costing.
- Average patient cost estimates for specific CMGs: Using tools like the Patient Cost Estimator[79] (PCE) [174].
- Patient-level micro-costing: The most granular, but data/resource-intensive, method.

E&W: neue, hochpreisige Leistungen: direkt von NHS-Providern

In England & Wales [42], the Drugs and Pharmaceutical Electronic Market Information Tool (eMIT) [175] or prices agreed by the Medicines Procurement and Supply Chain[80] (MPSC) should be used for pharmaceuticals in the secondary care (hospitals). For new or high-cost procedures excluded from national tariffs, prices should be sourced directly from NHS providers.

[79] CIHI's PCE (https://www.cihi.ca/en/patient-cost-estimator) provides average acute care hospital costs by jurisdiction, service type, and age group for patients on a typical treatment course. Cost estimates include facility and (in 7 jurisdictions) physician costs. Jurisdictional variations may affect comparability due to variations in care models and labour rates (Patient Cost Estimator Methodology Notes and Glossary [174]).

[80] The NHS Supply Chain catalogue is a digital platform listing all products and services procured by NHS Supply Chain, offering a single source of information including pricing, stock status, and alternatives for suspended items for NHS staff. The eMIT provides information about prices and usage for generic drugs and pharmaceutical products. NHS England's Medicines Procurement and Supply Chain (MPSC, formerly CMU) oversees secondary care medicines procurement via framework agreements.

New Zealand [45, 46] offers a unique economic nuance by specifying that if a hospitalisation is the main cost driver, marginal costs (the cost of producing one additional unit) should be used instead of the full average DRG-based unit cost, which includes overheads. Because inpatient drug-administration costs are already included in case-mix-adjusted DRG tariffs[81], using marginal (rather than average) hospital costs may markedly change the cost-effectiveness of interventions.

NZL: Hospitalisierung/ Kostentreiber → Grenzkosten statt DRG-Ø (Overhead exkludiert)

In Germany, the Institute for the Hospital Remuneration System (InEK) provides a calculation handbook [176] to derive cost per DRG case in hospitals, plus a catalogue and a database (aG-DRG-Report Browser) [177] with cost per DRG case including additional charges under the DRG system [178]. Furthermore, the DRG research group provides the DRG Webgrouper that applies the grouping rules of the German DRG system to calculate potentially reimbursed costs per DRG case including additional charges [179]. Germany [44] also has a separate, detailed average cost remuneration system for psychiatry and psychosomatics (PEPP), acknowledging its suitability for long-term treatments.

GER: InEK-Handbuch, aG-DRG-Report-Browser, DRG-Webgrouper. PEPP-System für Psychiatrie

Table 4-10 summarises the hospital valuation methods and key characteristics of each guideline.

Table 4-10: Overview valuation characteristics for hospital services in each country

Country	Primary valuation method(s)	Key Characteristics & Specificities
Australia [31]	Case-Mix (AR-DRG)	Highly structured: NHCDC for AR-DRGs (inpatient), URGs (emergency), and Tier 2 (outpatient).
Belgium [33, 34]	Per Diem	Uses RIZIV-INAMI data and specifies different rates for 6 stay types (acute care, burns, geriatrics, palliative, psychiatric, specialised/chronic)
Canada [35-37]	Case-Mix (CMG) & Per Diem	Four-approach hierarchy: 1) Per Diem, 2) CMG/RIW, 3) Patient Cost Estimator, 4) Micro-costing.
Denmark [38-41]	Case-Mix (DRG & DAGS)	Uses DRG (inpatient) and DAGS (outpatient). Recommends micro-costing if tariffs mask cost variation.
England & Wales [42]	Case-Mix (HRG)	Primary source is the NCC and NHS Payment Scheme.
France [43]	Case-Mix (HPG)	Prefers NCS unit costs; uses HRG tariffs if NCS data is unreliable.
Germany [44]	Case-Mix (DRG)	Uses the German DRG system and a separate PEPP system for psychiatry and psychosomatics.
New Zealand [45, 46]	Case-Mix (DRG)	Uses WIES-adjusted DRG tariffs. Specifies use of marginal costs if hospitalisation is the main cost driver.
Norway [47]	Case-Mix (DRG) & Per Diem	Uses DRG cost weights or NoMA's per diem (unit) costs for general and intensive care bed-days derived from official national data (Norwegian Directorate of Health's database – SAMDATA).
Scotland [48]	Per Diem	Uses Scottish per diem costs (NHS Cost Book); accepts English NCC data.
Netherlands [49, 50]	Mixed (Micro & Macro)	Prefers bottom-up micro-costing for procedures and uses top-down for broader units (bed days).
USA [51, 52]	Case-Mix (DRG)	Uses DRG reimbursement rates from HCUP or Medicare.

DRG…Diagnosis-Related Group, HCUP… Healthcare Cost and Utilization Project, NHS…National Health Service, NCC…National Cost Collection, NoMA…Norwegian Medical Products Agency, PEPP… Pauschalierende Entgeltsystem Psychiatrie und Psychosomatik/Remuneration System for Psychiatry and Psychosomatics, WIES…Weighted Inlier Equivalent Separations, DAGS…Danish Ambulatory Grouping System, CMG…Case-Mix-Groups, RIW…Resource Intensity Weights, URG…Urgency Related Groups, NHCDC…National Hospital Cost Data Collection, AR-DRG…Australian Diagnosis-Related-Groups

[81] WIES (Weighted Inlier Equivalent Separations) case mix system is applied to adjust DRG tariffs for complexity/severity, patient volume (when weighting multiple DRGs), and mechanical ventilation.

4.5.6 Residential Care, Home Nursing, and Home Care

Langzeit-/häusliche Pflege: heterogen & oft lückenhaft

The valuation of care provided outside traditional (acute care) hospital settings – specifically residential care, home nursing, and home care – reveals significant gaps and varied approaches in international guidelines. While a few countries provide detailed methods, many either subsume these costs under broader categories (e.g., healthcare services) or provide no specific guidance, reflecting the challenge of standardising valuation for these often decentralised and heterogeneous services.

AUS: explizite Methoden für stationäre Langzeitpflege & häusliche Pflege/ Krankenpflege

A minority of countries offer explicit methods for costing residential and home-based care, recognising their importance in the patient pathway. Australia [31, 32] recommends that the unit cost for residential care should be based on the daily ACFI subsidy (Daily ACFI subsidy + basic daily fee). Commonwealth Home Support Programme (CHSP) national average and similar ACFI-based subsidies for tailored care are recommended for valuation of home care and home nursing.

CAN: explizite Methoden für stationäre Langzeitpflege & häusliche Pflege

The Canadian guideline [35-37] recommends that residential care services should be valued in form of cost per day using RUG-III with CMI to adjust daily costs for resident complexity. As mentioned, this valuation approach is similar to the DRG-based valuation for hospital services. Resident payments should be excluded from the reference case. Home care should follow a time-based costing approach using public-sector hourly wages plus travel costs when fee schedules are unavailable.

DNK: KH-Methodik für kommunale, häusliche Pflege

Denmark [38-41] integrates these services into its broader public sector costing, valuing municipal home care using unit costs per effective hour from municipal salary data, applying the same rigorous methodology used for hospital services.

FRA: Ø-Tageskosten

The French guideline [43] recommends valuing these services according to the average daily cost of care in the NCS on care homes for dependent elderly people (ENC EHPAD) [180].

NDL: Referenzpreise aus Kostenstudien

The Dutch guideline [49, 50] values these services using reference prices based on costing studies provided in the costing manual similar to the valuation of other health services.

NZL, NOR, SCT, USA bewerten nach allgemeinen Prinzipien für Gesundheits-/Krankenhausleistungen

Several guidelines indicate that these services are included but should be valued using the general principles applied for healthcare or hospitals services, without sector-specific methods. New Zealand [45, 46], Norway [47], Scotland [48], and the USA [51, 52] all refer to the healthcare services for valuation, suggesting these costs are recognised but not giving them distinct methodological treatment.

E&W: Verweis auf Public Health & soziale Leistungen

A significant number of guidelines do not describe a specific valuation approach for these services as they include them in general healthcare service unit cost sources. England & Wales [42] direct guideline users to valuation methods for public health and social care services (see Section 4.5.9 Other Healthcare System-Specific Services).

4.5.7 Transport, Travel Expenses, and Ambulance

Transportkosten: Inklusion primär bei gesellschaftlicher Perspektive (DNK, FRA, NOR, NDL) + Deutschland

Präferenz: standardisierte nationale Tarife

The valuation of transport, travel, and ambulance services broadly splits along perspective lines: countries adopting a comprehensive societal perspective versus those with a more restricted healthcare system view. Among the five countries that include and value these costs (Denmark [38-41], France [43], Germany [44], Norway [47], Netherlands [49, 50]), four mandate a societal perspective (Denmark, France, Norway, Netherlands). The inclusion and valuation of these services reflect the understanding that access to care involves logistical and financial burdens on both the health system, patients, and relatives. The corresponding guidelines signify a strong preference for using standardised national rates or allowances to ensure consistency.

Transport and Travel

Reisekostenbewertung:

km-Pauschalen, Tarife, eigene Referenzpreise, Ø-Erstattungsbeträge

Denmark [38-41] recommends the use of the state's tax-free mileage allowance, requiring regional, municipal, and patient transport to be reported separately. The Norwegian guideline [47] mandates that transportation costs for travel to and from treatment should be done by using HELFO tariffs [140] and noting that costs are doubled for a round trip. The Dutch guidelines [49, 50] provide reference prices per km for each mode of transport (car, public transport, taxi, ambulance) and includes a fixed travel component in the cost of a home care visit. The French guidelines [43] recommend the use of average reimbursed amounts from national health insurance data and micro-costing for non-reimbursed transport. The German guideline [44] recommends the inclusion of these costs in the reference case but does not provide explicit information on how to cost them.

Ambulance

Krankentransporte:

AUS: Ø-Kosten pro Fahrt (Gesamtkosten ÷ Fahrten pro Jahr).

CAD: Vollkosten pro Fahrt (Fahrzeug, Personal, Overhead)

For ambulance services, only two guidelines provide valuation guidelines, typically using full operational costing. Australia [31, 32] recommends the inclusion of ambulance services if a medicine affects their use, valued as the mean cost per trip (Total annual costs ÷ total annual trips). Canada [35-37] provides detailed guidance, noting that costs vary by service type (emergency vs. transfer) and that for a societal perspective, full operating costs (vehicle, staff, overheads) should be used, calculated as Cost per ride = Total annual operating costs ÷ number of rides.

4.5.8 Productivity Costs, Patient and Caregiver Time, and Informal Care

Productivity Costs

Produktivitätskosten, Pat.-Zeit & informelle Pflege

Minderheit inkludiert Produktivitätskosten

meist FCA und HCA optional

A minority of countries mandate the inclusion of productivity costs in their reference case. Countries with explicit inclusion in their guideline are Canada [35-37], Germany [44], and the Netherlands [49, 50], all three applying a societal perspective. Their preferred methodology is typically the FCA, which values lost output only for the period needed to replace an absent worker (the friction period). Canada limits costs to the friction period until a worker is replaced using hourly wage data from Statistics Canada [181]. Germany recommends that in the reference case, losses should be valued at 80% of wage costs for a specific period. The Netherlands [49, 50] recommends calculating the value per hour based on average gross labour costs. The Canadian and

German guidelines [44] offer the option to apply the human capital approach (HCA) as an alternative for sensitivity analyses.

Berücksichtigung nur in zusätzlicher Analyse (nicht in Referenzmethode)

A strong majority of countries explicitly exclude productivity costs from their reference case, confining them to supplementary analyses or omitting them entirely. Guidelines from Australia, Belgium, Denmark, England & Wales, France, the US allow inclusion only in supplementary analyses. Among these, Australia [31, 32], Belgium [33, 34], and the US are more explicit on the valuation method. Australia and Belgium, if considered, recommend an HCA for short absence and a FCA for long absence. The US guideline [51, 52] recommends an HCA for formal labour, informal labour, and household production loss. US unit cost estimates are provided in Jiao and Basu [2023]. The French guideline [43] allows the author to choose the valuation method for productivity costs, but the selection needs to be justified.

explizite Exklusion in NZL & NOR (trotz Gesellschaftsperspektive)

New Zealand's [45, 46] and Norway's guideline [47] mandate the exclusion of productivity costs in the reference case. Norway [47], despite its societal perspective and inclusion of patient or relative travel time, still excludes other productivity costs. No explicit information is available for Scotland [48].

Patient and Caregiver Time and Informal Care

Pat..Zeit & informelle Pflege: Methoden meist intransparent bzw. nicht vorhanden

Half of the guidelines fully incorporate patient and caregiver time or informal care costs into their reference case, reflecting a commitment to capturing the full societal resource impact of an illness. Where inclusion is recommended, either in the reference case or in a supplementary analysis, valuation methods are often not fully transparent.

allgemeiner Bewertungsansatz: Ø-(Netto-)Stundenlohn für gesamte Zeit (Arbeit/Freizeit)

Canada [35-37], Denmark [38-41], France [43], Germany [44], the Netherlands [49, 50], and Norway [91] explicitly recommend the inclusion of patient and caregiver time or informal care in the reference case. Valuation of general patient or caregiver time is often based on a standard average (net or after-tax) wage rate, applied to all time regardless of its source (work or leisure). Travel time, not to be confused with travel costs, is consistently treated as a key element of patient and caregiver time. The Netherlands [49, 50] use standardised travel expenses which include the travel time costs and transport costs. Norway [47] also recommends the inclusion of travel time to and from treatment basing its valuation on HELFO tariffs [140]. Denmark recommends the consideration of patient and caregiver time but mandates the exclusion of informal care.

informelle Pflege analog zu Produktivitäskosten (CAD), FCA (NDL), GER (keine Methode aber Inklusion)

The Canadian [35-37] guidelines explicitly state that informal care cost should be included and valued like productivity costs, aligning with its societal perspective that also includes productivity costs. For informal care, the Netherlands [49, 50] uses a specific replacement cost method, valuing time at the hourly rate of a professional domestic care worker. The German guideline [44] recommends the inclusion of disease-related time invested by relatives in its reference case but does not provide explicit information on the valuation.

Table 4-11 gives a summary of the handling of productivity costs, patient and caregiver time, and outlines the rationale for the choice of approach.

Table 4-11: Overview of valuation of productivity costs and patient and caregiver time (including travel) in each country

Country	Productivity costs in reference case (Applied method)	Patient and caregiver time incl. travel in reference case (Applied method)
Australia [31]	* (HCA)	X
Belgium [33, 34]	* (HCA)	X
Canada [35-37]	✓ (FCA)	* (FCA or HCA)
Denmark [38-41]	* (NR)	✓ (Average after-tax wage)
England & Wales [42]	* (NR)	X
France [43]	* (NR)	✓ (NR)
Germany [44]	✓ (FCA)	✓ (Average net wage)
New Zealand [45, 46]	X	X
Norway [47]	X	✓ (NR)
Scotland [48]	NR	NR
Netherlands [49, 50]	✓ (FCA)	✓ (Standardised reference prices)
USA [51, 52]	* (HCA)	* (HCA)

✓ *…Yes, considered in reference case*

X *…Not considered*

* *…Considered only in supplementary analysis*

FCA…Friction cost approach, HCA…Human capital approach, NR…Not reported

4.5.9 Other Healthcare System-Specific Services

sonstige Leistungen: Public Health, Soziales, Psychiatrie, Palliativ

Other valued services in the guidelines contain mostly public health, social care, mental health, and palliative care. Their inclusion and valuation are strong indicators of a guideline's commitment to a more comprehensive perspective.

NDL detailliert (Psychiatrie, Reha, Behindertenhilfe)

The Netherlands [49, 50] provides the most detailed and methodologically diverse framework for other services, using a mix of micro- and macro-costing:

- Mental health care: Valued via reference prices from bottom-up micro-costing studies for contacts, days, and activities.
- Paramedical and rehabilitation services: Uses top-down macro-costing (total expenditure ÷ volume) to derive costs per consultation or day of care.
- Disability care: Also uses top-down macro-costing based on national expenditure data.

CAN, E&W, DNK, FRA, NZL, NOR mit spezifischen Vorgaben

Canada's [35-37] guideline also includes recommendations on the valuation of public health programmes, mandating valuation based on local budget data and adding a 20% overhead to direct costs, demonstrating a pragmatic approach to capturing full programme costs. The guideline from England & Wales [42], similarly to Canada, includes public health and social care services, relying on established sources like the PSSRU unit costs and local data.

Denmark's [38-41] guideline includes municipal services, valuing them using unit costs per effective hour from municipal salary data, applying the same rigorous approach as for health-care services.

spezifische Methoden für Public Health, End-of-Life & hochpreisige Notfallleistungen

The guidelines from France, Norway, and New Zealand provide guidance on specific, high-cost, or well-defined areas like end-of-life care or emergency medicine. France [43] provides guidance on high-cost emergency services, valuing them using NCS HPG unit costs and a specific tariff plus a flat-rate emergency fee. New Zealand [45, 46] provides specific guidance for palliative and terminal care, distinguishing between hospital-based care (valued using DRG tariffs) and community-based care (valued using per-day or per-visit rates). The Norwegian guideline [47] also provides specific guidance for palliative care, using a palliative care unit price set by NoMA based on DRG codes [183].

AUS nur qualitativ

4 Länder ohne Guidance

Most of the guidelines do not provide specific guidance for these broader services or include them in other costing domains. The Australian guideline [31, 32] mandates the exclusion of other community-based services (e.g., meals on wheels) from quantitative analysis due to data limitations and recommends that they be mentioned only qualitatively. Belgium [33, 34], Germany [44], Scotland [48], and the USA [51, 52] provide no specific guidance on further service categories.

4.5.10 Cross-Sectoral Aspects, Transfer Payments and Intangible Costs

sektorübergreifende Aspekte & intangible Kosten

Some cost categories and methodological aspects identified in the guideline do not fit neatly into previous domains, including cross-sectoral impacts, transfer payments, and intangible costs. The guidance on these elements further refines the boundaries of the reference case and highlights advanced methodological considerations for comprehensive societal evaluations.

Cross-sectoral Costs

NDL mit expliziten Methoden zu sektorübergreifenden Kosten: Bildung, Justiz

The inclusion of costs falling outside the traditional healthcare sector is rarely mandated. The Netherlands [49, 50] is the only guideline to provide explicit valuation methods for cross-sectoral impacts. It uses top-down macro-costing for the education sector (e.g., cost per day of schooling) and top-down micro-costing for the criminal justice sector (e.g., cost per criminal act). The costing manual lists also specific unit costs for services in these sectors.

Transfer Payments

Transferzahlungen in allen Ländern exkludiert (keine Ressourcenkosten)

All countries addressing transfer payments (welfare, financial aid, social security, pension payments etc.) exclude them from their reference case due to their non-cost-bearing nature. Consequently, no valuation approach is mentioned for transfer payments.

Intangible Costs and Leisure Time

intangible Kosten nicht auf Kostenseite (keine Methoden genannt)

These are non-monetary costs associated with the disutility of illness and treatment and are usually the most difficult to measure and value. The valuation of pain and illness can lead to double counting as these are intended to be captured within QALYs. The included guidelines do not provide valuation methods for intangible costs as a separate cost item on the cost side.

4.5.11 Lump-sum Payments and Overhead Costs

Pauschalen & Overhead selten explizit thematisiert

The valuation of lump-sum payments (fixed payment for a treating a patient in a DRG-system regardless of the acutal costs) and overhead costs (e.g., heating, cooling, and electricity costs for the entire hospital building) addresses two critical aspects of economic evaluation: the accuracy of unit costs or reimbursement tariffs as proxies for resource use, and the comprehensive accounting of all system-level resources required to deliver care. The guidance on these topics is sparse in all identified guidelines, indicating they are often handled implicitly within broader costing frameworks rather than as explicit methodological standpoints.

Lump-sum Payments

Pauschalen in BEL explizit exkludiert

The Belgian guideline [33, 34] is the notable exception: it states that lump-sum payments (e.g., for lab tests, imaging) should be excluded to avoid cost underestimation as these payments may not reflect actual resource use in practice. This highlights a critical concern that such payments may be set below the actual cost of providing the service, potentially making interventions that rely on these services appear artificially cost-saving.

Pauschalen in Leitlinien meist nicht erwähnt

Most other guidelines do not mention lump-sum payments separately. This implies that the nationally recommended costs (e.g., DRG-based unit costs, NHS Reference Costs) are accepted as the valid benchmark for valuation, regardless of whether they are structured as lump-sums or not.

Overhead Costs

Overhead-Kosten: selten explizit beschrieben

Overhead costs refer to indirect, shared resources like administration, management, utilities, and capital that are necessary for the functioning of a healthcare provider but are not tied to a specific patient procedure.

CAD: Inklusion (KH, Rettung, Public Health); für Public Health: 20% Aufschlag auf Direktkosten.

Guidelines of two countries provide explicit guidance on the valuation of overhead costs. Canada [35-37] recommends the inclusion of overheads in the cost calculations for hospital care, ambulance services, and public health programmes. For public health interventions, it recommends adding a 20% mark-up on direct costs to account for overheads. The Netherlands [49, 50] has the most detailed method, specifying that overheads (e.g., for administration, cleaning, management, IT) should be calculated using the preferred cost centre method or an alternative mark-up method. This reflects a commitment to include all direct and indirect costs reflecting full-cost accounting.

NOR: keine generelle Empfehlung, da methodisch herausfordernd

The Norwegian guideline [47] notes that currently there is no general recommendation concerning allocation and valuation of overhead costs, indicating a recognised methodological challenge without a consensus solution. For most countries, the lack of specific guidance suggests that overheads are embedded within the mandated national unit costs or tariffs. These published costs are typically derived from provider accounts that already allocate overhead, so their use implicitly includes these costs without requiring separate calculation by the analyst.

Mehrheit: implizit in nationalen Unit Costs/Tarifen enthalten

5 Discussion

hoher methodischer Entwicklungsstand in allen 12 Ländern

Unterschiede nicht nur technisch; geprägt durch Governance, Prioritäten, Datenkapazität & System

The synthesis of the guideline documents from the included 12 countries shows that they demonstrate a high level of methodological development in their health economic reference cases and costing process. While the guidelines across countries share a stable methodological core, their differences are not merely technical. Understanding these differences is essential because costing including unit cost development are not a mechanical step in HEE. Costing and the feasible reference case are shaped by governance, political priorities, (economic) capacity including data availability, and underlying philosophies about what the healthcare system is responsible for.

5.1 Foundational Principles and Areas of Convergence

Grundprinzipien & Konvergenz: CUA-Präferenz; Konsens zu lebenslangem Zeithorizont & rigoroser Unsicherheitsanalyse

The near-universal adoption of CUA as the preferred reference case reflects a shared reliance on a broadly utilitarian framework[82] for valuing health, using a "common currency" (the QALY) that facilitates cross-disease and cross-intervention comparability [11]. This is complemented by a strong consensus on other core methodological components such as a time horizon long enough to capture all relevant differences, and rigorous standards for uncertainty analysis. The latter is particularly significant. It demonstrates the understanding that decision-making occurs under uncertainty, and transparency about this uncertainty is crucial for robust healthcare decisions [184].

Doppelfokus auf Effizienz & kurzfristige Finanzierbarkeit.

Furthermore, the widespread requirement for a BIA alongside the cost-effectiveness analysis signals a dual focus on both efficiency and affordability (short-term financial sustainability). The country-specific BIA perspectives provide a clear map of financial decision-making responsibilities within each healthcare system, often requiring a more granular and multi-stakeholder analysis than the HEE itself.

The convergence around these principles creates a strong, shared foundation that enhances the credibility of decisions, the health economic discipline and provides a common language for international discourse.

Unsicherheitsanalyse: gemeinsamer Standard, aber methodische Tiefe variiert → e.g., Value-of-Information-Analyse

However, even these shared principles mask underlying differences. For example, although all countries call for uncertainty analysis, the sophistication of the recommended methods varies. Belgium's and the Netherland's adoption of VOI analysis marks a progressive step from merely measuring uncertainty towards actively managing it to inform research prioritisation and decision flexibility [33, 34, 49, 50, 100].

[82] Strohmaier et al. [2025] provide a treatise of the concept and application of Utilitarianism in health economics and in the decision-making context discussing advantages and disadvantages.

Similarly, discounting is universally required but contested. Some adopt a unified rate for costs and health outcomes, whereas others apply differential rates. This reveals unresolved disagreements and different preferences about intertemporal equity and how to value future health relative to current consumption. The choice of discount rate can strongly influence the cost-effectiveness of preventive interventions and chronic disease therapies. Furthermore, the differences have also an impact on international transferability of health economic results. Overall, these divergences highlight the extent to which methodological alignment still coexists with disagreement.

Diskontierung: einheitliche vs. differenzielle Sätze? → unterschiedliche Zeitpräferenzen & Bewertung zukünftiger Gesundheit

5.2 Differences in Costing Philosophies

The most significant divide observed across countries concerns how the guidelines conceptualise the purpose and feasibility of costing. Most jurisdictions adopt a pragmatic approach by recommending the use of tariffs, top-down costing where possible, or provide unit cost "databases" based on these approaches and apply bottom-up micro-costing, the costing gold standard [34, 71, 88], selectively when necessary (e.g., new technologies, highly variable resource use, or dominant cost components) [33, 34, 38-42, 44, 47]. This reflects not merely a resource or data constraint but reflects a policy view that HEE should be timely, feasible, and broadly aligned with real-world budgeting structures. From a methodological standpoint point of view, this reflects a pragmatic understanding of the fundamental trade-off between feasibility and accuracy [71, 88].

Kostenphilosophien: meist pragmatisch → Mehrheit mit Top-down Makro-Costing & Mikro-Costing selektiv

Trade-off zwischen Machbarkeit & Genauigkeit

In contrast, the Netherlands' [49, 50] micro-costing-first principle reveals a fundamentally different interpretation of opportunity cost. It challenges the premise of the efficiency-accuracy trade-off by suggesting that a consistently higher level of accuracy and precision is both possible and necessary for robust decision-making even when it requires substantial data infrastructure and analytical effort by generating genuine health economic evidence in the form of costing studies.

NDL: "Micro-Costing First!"

These divergent national approaches in costing reflect fundamental discussion points in the scientific literature on costing. First, there is no gold standard for the measurement of resource use [185]. Consequently, actual measurement methods are, with exceptions, often based on practicality and data availability, relying unsystematically on methods such as administrative data, patient questionnaires, guideline-based resource measurement, or expert inputs [186-188]. The lack of appropriate methods and its application is due to challenges in the time-consuming measurement process and the limited research on this topic [185, 186, 189].

wissenschaftliche Reflexion: Methoden of pragmatisch & teils unsystematisch → mehr Forschung notwendig

Second, no single, universally accepted unit costing methodology exists to value resource use [8, 83]. Unit costs are highly sensitive on the calculation method, creating heterogeneity [8]. This methodological inconsistency prevents meaningful comparison of cost estimates across studies, sectors, countries and even within countries, which can compromise the validity of study conclusions and ultimately decisions in the healthcare system. To arrive at valid cost estimates, appropriate guidance on measurement methods and unit cost calculation is paramount [83, 185].

keine einheitliche Methode für Unit Cost

In response, the PECUNIA project offers a comprehensive, integrated solution to these longstanding methodological challenges [8, 83, 185]. To solve the problem of resource identification and description, it developed a standardised international list of services using the Description and Evaluation of Services and Directories (DESDE) coding system to create unambiguous definitions, eliminating the ambiguity where the same service name refers to different activities in different countries [190]. For resource use measurement, it designed the PECUNIA RUM Instrument [185], a tool that ensures the units of data collection are perfectly aligned with the units required for costing. For resource valuation, PECUNIA created standardised costing templates to harmonise the calculation of unit costs across sectors and countries. A set of first reference unit cost estimates developed for six countries based on these templates were then compiled into a multi-sectoral, international compendium [9]. By linking these three components, PECUNIA provides a unified framework to ensure resource use data is consistently identified, accurately measured, and comparably valued across sectors and national borders. However, future research must focus on applying and validating the PECUNIA tools to further test their feasibility, robustness, and acceptability in practice [191]. The PECUNIA resource unit cost (RUC) templates are currently used by a research project, STREAMLINE (2023-2025), which aims to test them further, particularly for primary data collection [192].

PECUNIA: Ansatz gegen methodische Heterogenität

Methoden zur Identifikation (DESDE), Messung (PECUNIA RUM-Instrument), Bewertung (standardisierte Templates & Unit Cost-Kompendium)

Validierung & Praxistest laufen (STREAMLINE-Projekt).

Ultimately, all these aspects create a methodological tension between two paradigms:

methodologischer Konflikt

- The pragmatic paradigm aims to generate timely, policy-relevant estimates aligned with existing payment structures.
- The precision-oriented paradigm views costing as an exercise in capturing true resource use, regardless of administrative convenience.

pragmatisch (zeitnah, policy-relevant) vs....

präzisionsorientiert & valide (Abbildung wahrer Ressourcenkosten)

Neither approach is inherently superior, but each reflects a different relationship between HTA, health economics, decision-making, and data capabilities. The tension between these paradigms suggests that true international harmonisation of costing methods remains unlikely unless data availability becomes more standardised or the policy goals of HTA systems converge.

5.3 Perspective and Cost Inclusion

Perhaps the most consequential difference across guidelines is the choice of perspective. It is consequential because the perspective determines the included costs [68, 79, 86, 87]. Perspectives range from narrow healthcare perspectives to broad societal perspectives that include productivity, time costs, informal care, and even sectoral impacts beyond health, such as education, emyploment, social care, and justice sector.

Perspektive als Schlüsselvariable: bestimmt Kostenumfang – (Gesundheitssektor bis Gesellschaftsperspektive)

These differences are policy choices rather than methodological necessities. They reflect:

Perspektive als Policy-Entscheidung:

- What each system considers a legitimate cost (direct healthcare costs, direct non-healthcare costs, indirect/productivity costs, intangible costs, cross-sectoral costs etc.)

Was gilt als legitime Kosten?

Wer trägt relevante Lasten?

- Which actors are recognised as bearing relevant burdens (patients, healthcare payer, healthcare system/sector, the state/government, society as a whole), and
- How closely HTA and health economics is tied to the healthcare budget versus broader societal welfare.

Wie eng an Budget vs. gesellschaftliche Wohlfahrt gekoppelt?

The Netherlands' operationalisation of cross-sectoral costing illustrates a conceptual commitment to welfare maximisation [49, 50]. Most other countries' exclusion of cross-sectoral impacts illustrates the practical limits of working within siloed budget structures.

Perspektive formt Verteilungswirkung, Sichtbarkeit von Pat.-Last & Effizienz von Interventionen

This discrepancy shows that the perspective is not just a technical parameter. The perspective is a major factor when establishing a reference case and needs special attention, because it shapes the distributional consequences of decisions, the visibility of patient and caregiver burden, and the types of interventions that appear efficient. An analysis from a societal perspective, like the Dutch perspective [49, 50], will be inherently more complete in a societal sense than one conducted for NICE in England & Wales [42], as the former includes productivity losses, patient time, and costs in other sectors like education and criminal justice [68, 193].

gesellschaftliche Perspektive theoretisches Ideal

Praxis: Budgetrealität dominiert

The choice of perspective also raises a fundamental question for policymakers [11]. Should the objective of HEE be to maximise health from a fixed healthcare budget, or to maximise overall societal welfare, even if that implies justifying resource transfers from other government departments? The near-universal choice for the former suggests that while the societal perspective is a theoretical ideal, its implementation is often constrained by the political reality of segmented government budgets and the practical challenges of quantification [8, 84].

Implikation für neue Leitlinien: Perspektivwahl explizit machen & begründen – vermeidet Inkonsistenz

Countries developing, implementing, or revising reference cases and costing guidance should make perspective-related choices explicit. Without transparency about the policy rationale underpinning methodological decisions, not only does costing guidance risk appearing inconsistent, but also decisions may seem contradictory. For jurisdictions with a narrow perspective, a supplemental societal analysis may represent best practice and serve as a starting point for providing a comprehensive picture including cross-sectoral costs.

5.4 Data Availability as a Determinant of Methodology

Dateninfrastruktur als Costing-Methodentreiber: Länder mit reichen Daten ermöglichen strukturierte Hierarchien & höhere Granularitä

Although the guidelines adhere to strict EbM principles regarding evidence on clinical effects, a consistent pattern across included guidelines reveals that a country's costing process is fundamentally shaped by the capabilities of its underlying data infrastructure. Systems with rich and accessible (administrative) data for measuring resource use or more systematic national unit cost sources for valuation (e.g., the Netherlands, Belgium, Germany, England & Wales) prescribe structured, hierarchical evidence retrieval and allow for greater granularity. For example, the Netherlands' ability to advocate for their costing paradigm is likely underpinned by a sophisticated data infrastructure that supports such detailed work.

Conversely, health systems that are more fragmented rely more heavily on pragmatic, top-down or hybrid methods using tariffs and expert opinion, as their data environment cannot support the same level of detail. Consequently, there is a widespread and explicit endorsement of RWD from claims, hospital records, and administrative databases to accurately capture routine care and to balance the limited external validity of resource use data from RCTs. Similarly, the frequent citation of clinical and treatment guidelines in countries like Canada [35-37], New Zealand [45, 46], the Netherlands [49, 50] and the USA [51, 52] to define standard practice and the associated resource use can be seen as another pragmatic adaptation, using a consolidated evidence base to compensate for a lack of universally accessible, granular primary data.

Pragmatismus bei Datenlücken: stärkere Nutzung von Tarifen, Expert:innenenmeinung, RWD, klinischen Leitlinien → Kompensation fehlender granularer Primärdaten

Almost every guideline emphasises local data adaptation. This highlights that HEA and decision-making is contextual and no one-size-fits-all approach exist. Expert opinion for the measurement and valuation of resources is generally accepted only to complement, validate primary data, or fill gaps where empirical data is lacking. Some guidelines specify a set of conditions, such as expert selection criteria or the detailed method to collect the expert opinions, for expert panel use in HEE (Australia [31, 32], Belgium [33, 34], Canada [35], England & Wales [42], France [43], and Scotland [48]).

lokale Adaption als wichtiger Grundpfeiler

The heavy reliance on case-mix systems (DRGs, HRGs, HPGs, CMGs) for valuing hospital (inpatient) care across all guidelines is only possible because such systems are well-established in almost every developed healthcare system. Conversely, the inconsistent and often absent guidance on valuing community care, social services, and residential care points to a common data gap. These sectors frequently lack the standardised, granular cost data available in acute care.

DRG als Rückgrat, aber systematische Datenlücke außerhalb Akutversorgung

In summary, variation in costing guidance reflects not only methodological preference but also:

- Maturity, readiness, and accessability of data systems.
- Integration of costing standards across (care) sectors.
- Availability of national (unit) cost databases.
- The technical capacity of research institutions (e.g. universities, etc.) and HTA agencies.

Determinanten der Methodenvarianz: Datenreife, sektorale Integration, nationale Kostenkataloge & technische Kapazität

Methodological guidelines cannot be developed in a vacuum. They must correspond with the data reality of the healthcare system they serve. This suggests also that attempts to harmonise costing methods internationally must account for the underlying reality that methodology is downstream of data availability, which varies from country to country.

Leitlinien müssen Datenrealität des Systems entsprechen

5.5 Considerations for Costing Aspects in an Austrian Health Economic Evaluation Guideline

The development and implementation of a national HEEG, which integrates a reference case with a specific costing approach, necessitates measures that go beyond the synthesis of current international guideline practices. It requires identifying the conceptual choices that shape a reference case and costing approach, understanding methodological trade-offs, and determining which setup best aligns with Austria's institutional, organisational, legal, and policy environment. This report shows that decision- and policymakers and HTA and health economic experts must make explicit choices on several key issues.

Implikationen für Österreich: konzeptionelle Grundsatzentscheidungen identifizieren, methodische Trade-offs verstehen, Konnex zu österr. Institutionen, Recht & Policy herstellen

Perspective (matters) – Costs for Whom?

Will the primary perspective be a strict healthcare perspective (e.g., Belgium [33, 34]), a broader societal perspective (like the Netherlands [49, 50]), or a hybrid (e.g., social healthcare insurance community such as Germany [44]) that includes some form of productivity losses but excludes patient travel time? This is the most consequential decision as the perspective is strongly connected to the inclusion and handling of non-straightforward costs and resource use (measurement). Especially if a societal perspective is deemed important.

Perspektive – Kosten für wen? Gesundheitssektor. gesellschaftlich oder hybrid?

What is therefore the Austrian stance on non-straightforward costs such as productivity costs? The inclusion of productivity cost is the most unresolved in theory but also in practice demonstrated by the included guidelines [73]. Generally, the purpose of inclusion of indirect cost is to represent the value of lost economic output mainly due to morbidity from a societal perspective [75, 76, 193, 194]. However, there is no (scientific) consensus on the best approach to identify and measure this impact [33]. The iMTA Productivity Cost Questionnaire (iPCQ) [117] or the Work Productivity and Activity Impairment (WPAI) [195] are validated tools to measure productivity losses.

Produktivitätskosten – österr. Position?

Theoretisch & praktisch ungelöst bzw. kein Methodenkonsens

The inclusion and valuation of patient and caregiver time including informal care, other patient costs (transport) and unrelated future medical costs is a normative, not just a technical, question. In the literature and from a policy perspective, there is an understanding that direct non-healthcare costs should be treated as foreign to government or healthcare budgets [75, 76, 193, 194]. Patient groups may advocate for their inclusion, while payer institutions may resist, although it is a real cost.

Pat.-Zeit & -kosten → normative Frage und oft „fremd" für Gesundheitsbudget

What is the healthcare decision- and policymakers' stance on cross-sectoral costs? This report showed that the Netherlands stands alone in its rigorous operationalisation of the societal perspective, formally including cross-sectoral impacts on sectors like education and justice. The Dutch reference case argues [49, 50] that an intervention that reduces crime or improves school attendance creates real value for other ministries and policy sectors, and this should be recognised. The tension between a limited perspective and a universal perspective highlights a fundamental question for policymakers: Should the objective of HEE be to maximise health from a fixed budget, or to maximise societal welfare, even if that implies resource transfers from other government departments [11]? The almost universal choice for the former suggests that while the societal perspective is an ideal, its implementation is often constrained by the reality of segmented government budgeting and the

Sektorübergreifende Kosten – Position?

Praxis: Sektorgrenzen & Quantifizierungsprobleme limitieren Umsetzung

formidable practical challenge of accurately quantifying these cross-sectoral effects [8, 84].

sektoraler Ansatz sehr herausfordernd → Kosten sensitive in Hinblick auf Methode

The consideration of cross-sector costs is associated with the "novel" sectoral costing approach [8]. The sectoral approach faces challenges, some shared with the functional approach and others unique to its structure [83]. A core shared challenge is the reflection of true opportunity costs [11], and both systems struggle with heterogeneous methodologies for key processes like overhead allocation [88, 89], making cost estimates sensitive to the chosen costing approach.

Perspektive – Spielraum & Ideal: Wahl lässt viel Gestaltungsspielraum

sissenschaftliches Ideal: globale Perspektive (alle Kosten, alle Sektoren)

explizite Positionierung nötig

In summary, the choice of perspective and included costs leave a lot of room for manoeuvre. While the sectoral costing approach provides a superior method for aligning costs with a chosen perspective, researchers must critically examine the perspective itself. A scientifically rigorous global perspective compels the inclusion of all costs, everywhere. This ensures that the analysis is guided by the universalist principles of scientific inquiry. Recognising the state's appropriation of the societal perspective as a normative act is crucial. By championing a more global perspective as the scientific ideal, health economics can strive to produce evaluations that are not only technically sound but also ethically grounded and epistemologically complete. A clear position on all perspective- and cost-related aspects is required but depends also on data availability, methodological capabilities, and the will to include these costs.

Approaching the Costing Approach(es)

Kostenphilosophie – Goldstandard (Mikro-Costing-Ideal) vs. Pragmatismus (pragmatischer Mix)

Besides the perspective, the costing philosophy is also a major discussion point. Austria must decide whether to pursue a gold-standard micro-costing approach, as seen as an ideal in the Netherlands [49, 50] or a pragmatic framework like those of Canada, Germany, or England & Wales. This decision is critically dependent on data availability and funding. Currently, systematic access to administrative cost data for HEA in Austria is limited, especially when compared to countries with established national unit cost databases or other administrative (cost) databases.

Langfristziel: nationaler Unit Cost-Katalog mit klarer Governance & Aktualisierung

Nevertheless, preliminary work for the Austrian context exists and includes the DHE Unit Cost Online Database [6, 7], Austrian-specific publications addressing unit costs [3, 4, 7], and the PECUNIA Project to calculate unit costs that are comparable across countries and sectors [8]. The long-term objective should be the creation of an actively maintained national unit cost catalogue or access to cost and resource data, supported by a clear governance and update process.

Empfehlung: ausgewogener Ansatz:, welcher Rigorosität mit Machbarkeit verbindet

Overall, a balanced approach is recommended as optimal. This would mandate micro-costing for high-impact technologies or dominant cost drivers, while permitting pragmatic macro-costing for other resources. This ensures methodological rigour where it matters most, while remaining feasible within the current Austrian data landscape and building towards a more robust future infrastructure.

Further Aspects

weitere Schlüsselfragen

There are further, non-trivial, and impactful questions that need to be answered:

- Will the guideline value resources based on tariffs or fees (reflecting budgets), if available, or strive for attempts to approximate true economic cost (e.g., costing studies), acknowledging the latter is more resource-intensive?

  Tarife (Budget) vs. ökonomische Kosten (aufwendige Studien)?

- Should the costing of medical devices adhere to lifecycle costing like in New Zealand [45, 46] instead of a simple acquisition-price approach?

  Lebenszykluskosten für Medizinprodukte?

- Which approach should be used to value productivity costs? There is no clear consensus on the best approach to measure productivity impacts [74, 76-78]. Some scholars favour the FCA over the HCA, as it yields lower estimates of productivity loss [53, 74]. This fundamental divergence means that the cost-effectiveness of interventions affecting working-age populations can vary dramatically depending on the jurisdiction, potentially creating a systemic bias in how the value of these treatments is perceived. However, the choice of the approach has not only an impact on decision-makers. Comparing productivity costs across studies remains challenging due to the application of different valuation methods.

  Produktivitätskosten – FCA vs. HCA? Methodenwahl beeinflusst Ergebnisse signifikant

- How to handle confidential discounts for pharmaceuticals? The English & Welsh model [42] of using the list price in public analyses and the discounted price in confidential decision-making may be a compelling approach to balance transparency and negotiation.

  Umgang mit vertraulichen Informationen?

- Should the guideline adhere to widespread costing standards regarding the exclusion of transfer payments and intangible costs like pain and suffering? If yes, a clear argumentation is key and not just referring other guidelines. For example, the primary rationale to exclude intangible cost must be the critical need to avoid double-counting [44]. Since the disutility of illness is captured by the QALY on the effect side, placing a monetary value on the cost side would distort the analysis. Costs should capture resource use, while QALYs capture health outcomes and their associated burden [79, 80].

  Transferzahlungen & intangible Kosten: Exklusion (Doppelzählung mit QALYs vermeiden) klar begründen

- How should equity concerns be addressed within the guideline and costing process? A potential approach is distributional CEA (DCEA). DCEA asks the question “Who bears the costs, and who gets the health benefits?”. DCEA requires much more granular costing data, because it investigates and applies subgroup-specific costs [196].

  Equity: Verteilung von Kosten & Nutzen? DCEA als Option – erfordert aber granulare Daten

All the discussed aspects are not exhaustive. A debate on methodological but also practical challenges with Austrian stakeholders is necessary to define what kind of aspects are deemed important and to clarify addressed issues.

Stakeholder-Debatte notwendig

6 Limitations and Outlook

6.1 Limitations

Limitationen:

This report is subject to several limitations inherent in its design and scope. Primarily, the project evolved significantly from its initial aim of focusing on unit costs to a systematic analysis of comprehensive costing methodologies and reference case principles in international guidelines. Whilst this shift was necessary to establish a robust foundational framework for Austria, it consequently meant that the detailed investigation of unit cost programmes, unit cost methodologies and Austrian-specific unit cost data sources and their practical application was formally postponed to a subsequent phase of research. Therefore, this report provides the essential methodological foundation regarding an Austrian health economic reference case and costing process for a future Austrian HEEG but does not specify unit-cost-specific aspects in full detail.

ursprünglicher Fokus erweitert auf Grundlagen gesundheitsökonomischer Referenzmethoden & Kostenprozess

Unit-Cost-Details & österr. Datenquellen auf Folgephase verschoben

Furthermore, the analysis was based on a comprehensive and exploratory hand search and not on systematic literature research commonly used to answer methodological questions in the HTA and health economics context. Furthermore, the literature was limited to published English- and German-language versions of guidelines. Guidelines or costing manuals in other languages were not the focus due to language barriers. The focus was also exclusively on the reference case principles and costing processes described in the guidelines. We did not verify how consistently these principles are applied in real-world submissions to respective HTA or decision-making bodies, which may differ from the theoretical standard.

Handsuche (kein SR), nur engl./dt. Leitlinien

keine Validierung der Umsetzung

The data extraction process, while comprehensive, presented a challenge for full double-checking due to the volume of qualitative information of the guidelines and the complexity of the extraction framework (which included both pre-defined and ad-hoc categories). To ensure the validity and reliability of the extraction despite this constraint, two key measures were implemented. First, the categorical framework of the extraction categories was critically appraised and confirmed to align with the study's research objectives. Second, the methodological consistency of the data extraction process was ensured through a pilot phase. The suitability of the extraction categories for addressing the core research questions was validated using a subsample of five out of the 12 included countries. Following this validation, the established categories were systematically applied to the remaining seven countries without further iterative refinement.

Datenextraktion: kein vollständiges Double-Checking

„nur" Pilottest an 5 von 12 Ländern, dann systematische Anwendung auf restliche 7 Länder

Finally, whilst the review covered 12 diverse countries, the selection was not exhaustive. Other jurisdictions may employ innovative costing approaches not represented in this analysis. The findings are thus a synthesis of international best practices rather than a fully comprehensive global consensus.

Ergebnisse repräsentieren „nur" internationale Best Practices

6.2 Outlook and Future Research

Nächste Schritte: Fokus auf Österreich

The findings of this report create a foundation for future work in the Austrian HTA and health economic context. The immediate and most critical next step is to initiate the postponed analysis of Austrian unit cost sources. This involves mapping and, where necessary, critical appraisal of Austrian equivalents of the key international data sources identified in this report, such as the Austrian DRG system (leistungsorientierte Krankenanstaltenfinanzierung – LKF), reimbursement code for pharmaceuticals (Erstattungskodex – EKO), or other sources such as the DHE Unit Cost Online Database or unit costs from the PECUNIA Project. In the upcoming project, the quality criteria for costing data defined in the first part of the report, such as practicability, completeness, and accessibility, should be systematically applied to assess identified Austrian data sources.

Empfehlung: Entwicklung österreichischer Referenzmethoden und Kostenrahmens

Subsequently, a conceptualisation of a possible Austrian reference case or costing framework, followed by its pilot application, are recommended. This would involve adopting relevant costing aspects and recommendations analysed in this report to the Austrian context and selecting a case study intervention to conducting a first costing process. This practical exercise would serve to validate the proposed Austrian framework, identify implementation challenges, and allow refinement of the proposed reference case and costing framework.

methodische Weiterentwicklung notwendig

Looking further ahead, this foundational work could support more advanced methodological developments, such as the development of standardised national valuation sets for further societal cost components in addition to national hourly rates for informal care or a standard friction period for productivity costs as developed by the PECUNIA project.

Bericht liefert strategische & methodische Grundlage für Gesundheitsökonomie in Österreich

In conclusion, this report provides the necessary strategic and methodological direction to advance HEE in Austria. By first establishing a room for manoeuvre for a potential Austrian HEEG, if offers a basis for developing more efficient, transparent, and accountable healthcare decision-making.

7 Conclusion

Bericht zeigt universell anerkannte Aspekte, aber Anwendung offenbart Gestaltungsspielraum

This comprehensive review of costing approaches in international health economic guidelines provides a path for advancing the health economic methodology and the standardisation of costing methodologies in Austria. The analysis demonstrates that whilst a core set of principles, such as a defined perspective, a toolbox of analytical techniques, or the general methodological transparency, generally recognised universal endorsement, their application reveals a spectrum of potential methodological room for manoeuvre.

Perspektive als primärer Filter

The critical divergence amongst included countries lies in the definition of the reference case perspective, which acts as the primary filter for all subsequent costing decisions. The choice between a narrow healthcare system perspective and a broader societal perspective reflects a fundamental policy preference in each country.

robuste Grundlage für künftige Referenzmethode & Kostenerfassungsmethode

For Austria, this report proposes a robust foundation for a potential future health economic reference case and costing approach. By first establishing these rigorous "rules of the game", this work provides the essential foundation upon which to build the next, crucial phase: the development of a systematic framework with robust, transparent, and nationally relevant Austrian cost data.

konsistente Anwendung erhöht Transparenz, Vergleichbarkeit & Verantwortlichkeit

In a further step, the detailed overview provided constitutes a blueprint for the development and implementation of an Austrian HEEG. The consistent application of the whole framework will increase transparency, comparability, and accountability in healthcare decision-making, ensuring that resources are allocated efficiently.

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