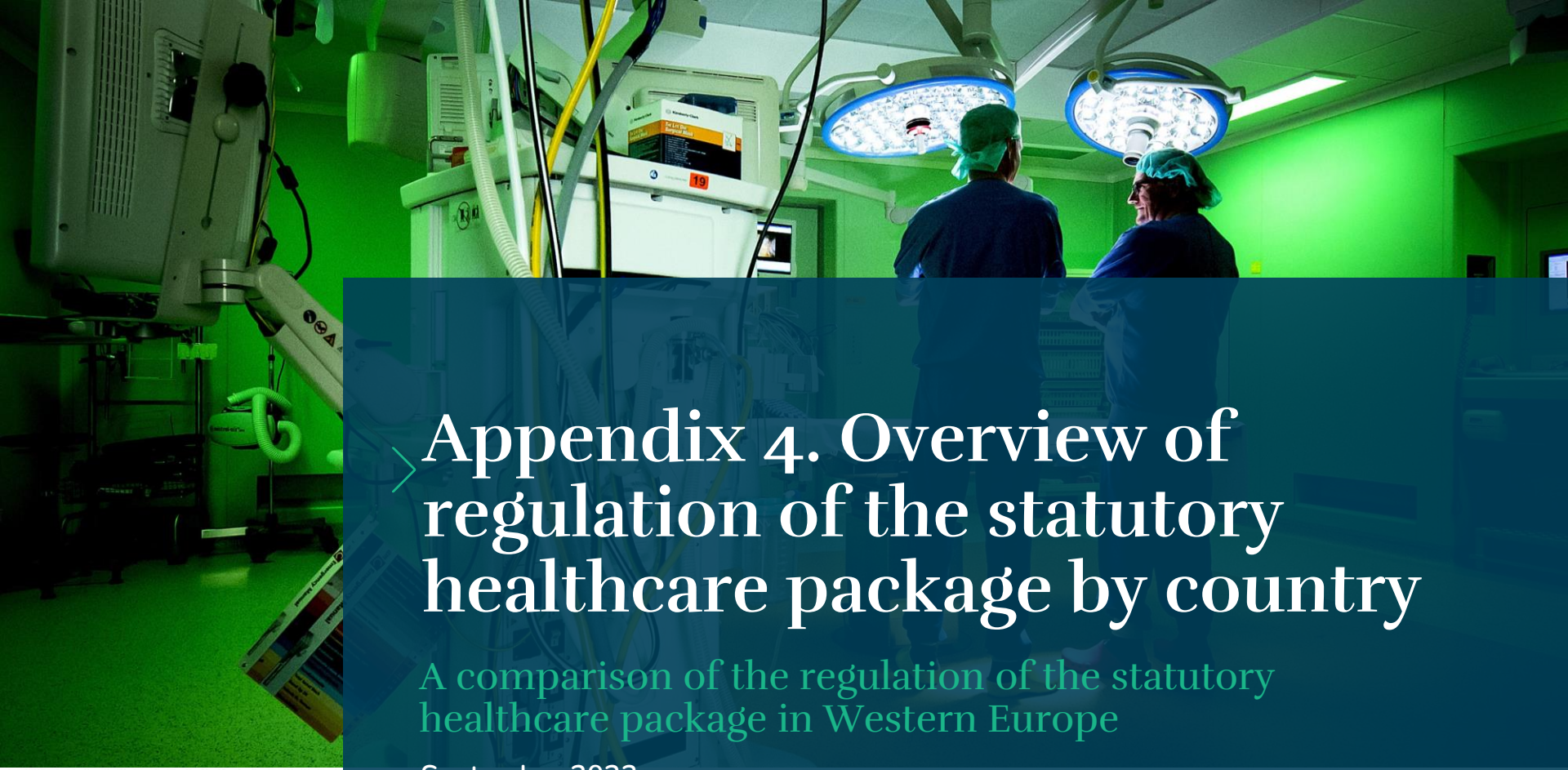

Appendix 4. Overview of regulation of the statutory healthcare package by country

A comparison of the regulation of the statutory healthcare package in Western Europe

September 2023

SiRM. Strategies in Regulated Markets

The Netherlands

General overview of the healthcare system and its statutory healthcare package for curative care

Type of healthcare system

- Before 2006 the Dutch healthcare system was mainly Bismarckian for those with incomes below a certain threshold (roughly 1.2x an average wage income) and private insurance for all others.
- Since 2006, a single-mandated health insurance scheme has covered the entire population, with possible extra insurance for dental care and physiotherapy.
- The new 2006 system introduced managed competition, giving consumers a free choice of insurer to trigger competition. The government now has a more distant role, supervising and facilitating three health markets: health insurance, healthcare purchasing and healthcare provision. Dutch citizens can switch insurers annually, and insurers must accept anyone who applies.

Coverage[1]

- **Breadth**: Basic health insurance is obligatory for all Dutch residents. Children under 18 are insured free of charge but must be included in one of the parents' plans.
- **Scope**: The basic health insurance package covers essential medical care, including primary and mental health care. Some treatments are excluded (e.g. elective procedures without medical indication or more than three IVF rounds[2]).
- **Depth**: Primary care is free at the point of delivery. All users aged 18+ must pay a mandatory annual deductible for other care types covered by basic health insurance.

Out-of-pocket (OOP) payments

- For basic health insurance, a compulsory deductible of €385 is levied on all healthcare expenditures except GP, maternity, home nursing and integrated care (for diabetes, COPD, asthma and cardiovascular risk management).
- In addition, consumers can opt into a voluntary deductible that varies between €100 and €500 per year; the higher the chosen deductible, the greater the discount on their health insurance premium.

1. Breadth: *who* is covered. Scope: *what* is covered. Depth: *how much* is covered.
2. In-vitro fertilisation

Main actors concerned with public curative-care coverage

• The Ministry of Health, Welfare and Sport (VWS) broadly determines the standard package's cover provision (i.e. which care type is reimbursed under what conditions), defined in legislation and regulations. • For specific healthcare treatments, the National Healthcare Institute (ZIN) has its own legal authority, requiring no decision from VWS.	**Decision-making body** VWS[1]	**HTA-body** ZIN[2]	• ZIN provides can review and issue a position[4] on reimbursing treatments, primarily in response to providers' and/or insurers' requests.[3] In the case of a stance, ZIN has its own legal authority, requiring no separate decision from VWS. • ZIN also advises VWS about the basic package's nature, content and scope - although the minister ultimately decides whether to follow these recommendations.
• Medical associations are responsible for developing and adapting guidelines and/or care standards. • Medical professionals decide which care type is most suitable for each patient in their day-to-day care.	**Providers / professionals**	**Purchasers / insurers** Healthcare insurers	• Healthcare insurers monitor whether healthcare providers' treatments comply with the SW&P[5]-criterion. Disagreements with care providers can be decided in court. • Healthcare insurers can request ZIN's interpretative stance on specific treatments.

1. Ministerie van Volksgezondheid Welzijn en Sport 2. Zorginstituut Nederland 3. Associations of professionals, the minister of VWS, and ZIN itself can also submit requests. This does not occur often. 4. In Dutch: 'standpunt' 5. Stand van de Wetenschap en Praktijk / State of Science and Practice'.

Criteria in the decision-making process

Role of the HTA-body (ZIN)

- ZIN can provide a legally-binding decision on treatment reimbursement at a provider's and/or insurer's request. ZIN can also initiate this process independently.
- ZIN advises VWS about the benefits package's nature, content and scope, but the minister ultimately decides whether to follow these recommendations.

Criteria used by the decision-making body (ZIN)

State of Science and practice (SWP[1]) assessment framework	• The SWP criterion determines whether care meets the standard of evidence, i.e. is proven at a group level to demonstrate sufficient effectiveness. • Although the assessment is based on scientific substantiation, it also considers evidence-in-practice.[3] • ZIN follows the principles of Evidence-Based Medicine (EBM) to determine whether care meets the SWP criterion.
Current practice of care[2]	• This criterion assesses whether care falls within a particular professional group's domain and whether that group deems it within its expertise area. It focuses on the type of care rather than its specific treatment methods, providing a general indication of its range.

1. Stand van Wetenschap en Praktijk 2. Plegen te bieden 3. Various aspects of the assessment account for healthcare providers' and users' expertise and experience.

Inclusion and exclusion of care types

		Inclusion of care types	Exclusion of care types
Inpatient	Procedures	• The inclusion of new treatments into the benefits package is primarily restrictive, except for outpatient drugs, expensive drugs and specific curative care types.[1] The legislator relies on healthcare providers, healthcare professionals, health insurers and care offices to provide treatments that fulfil the SWP criterion. • Thus, healthcare professionals are responsible for assessing the effectiveness of new treatments, determining whether a treatment's effectiveness is sufficiently proven and adopting new ones every few years in treatment guidelines. • Healthcare providers and health insurers (primarily) can request ZIN's position on whether care should stay within the insured benefits package. In some cases, ZIN initiates its decision without an external request.[2] • ZIN's board[3] ultimately makes coverage decisions.	• The Efficiency Studies Programme is run by the Netherlands Organisation for Health Research and Development (ZonMw) and evaluates (cost-) effectiveness in practice. ZonMw funds research on existing healthcare efficiency and effectiveness as part of this programme. • In addition, associations of healthcare providers, professionals and insurers set up a national programme in 2019 to evaluate the effectiveness of curative care treatments (ZE&GG[4]). • ZIN is also committed to cyclical coverage management[5] by following the care lifecycle in the basic benefits package (e.g. horizon scanning and risk-based analyses identifying redundant care).
	Medical devices		
Outpatient	Procedures		
	Medical devices		

Non-restrictive inclusion
Partially restrictive inclusion
Restrictive inclusion

1. E.g. physiotherapy and some other types of allied healthcare 2. E.g. based on healthcare expenditures. 3. Raad van Bestuur 4. Zorgevaluatie & Gepast Gebruik 5. Cyclisch pakketbeheer

Sweden

General overview of the healthcare system and its statutory healthcare package for curative care

Type of healthcare system

- Sweden's has a decentralised universal health system: healthcare is nationally regulated and locally administered.
- Funding comes primarily from regional- and municipal-level taxes.
- The Swedish National Healthcare Services are public and private. Public healthcare is managed, commissioned and provided by regions or municipalities. Private healthcare provision is either under regional contract (and thus covered) or not under contract (i.e. patients pay the full cost).
- In 2017, approximately 13% of employed residents had private supplemental health insurance, largely for greater access to private specialists.

Coverage[1]

- **Breadth**: All residents are automatically covered for health services.
- **Scope**: Covered services include inpatient, outpatient, dental, mental health, long-term care and prescription drugs. However, no nationally defined benefit package exists because the responsibility for organising and financing healthcare rests with regions and municipalities; thus, services vary throughout Sweden.
- **Depth**: Health services are either freely available or subject to nominal co-payments.

Out-of-pocket (OOP) payments

- Regions set co-payments for outpatient visits and hospital stays, while the national government determines pharmaceutical and dental benefits.
- In 2021, fees ranged from €10-30 for a primary care visit to €40 for a specialist visit (less with a referral) and €10 per day for hospitalisation. User fees for medical consultations are capped at €115 per year and at €235 per year for prescribed medicines.
- Exemptions for user charges apply to people under 20, older people and pregnant women.
- Preventive services (e.g. maternity care, immunisations and screenings) do not require co-payments.

1. Breadth: *who* is covered. Scope: *what* is covered. Depth: *how much* is covered.

Main actors concerned with public curative-care coverage

• The Ministry of Health and Social Affairs is responsible for overall healthcare policy and regulation and sets budgets for government agencies and regional grants, working in concert with nine national government agencies (including the SBU and Socialstyrelsen).	**Decision-making body** Ministry of Health and Social Affairs	**HTA-body** SBU[1]	• The SBU is an independent national authority the government has tasked with assessing healthcare and social service interventions.[4] The SBU reviews and evaluates new and existing treatments and medical devices. The Ministry, other Swedish agencies and individuals can propose topics to the SBU for assessment. • Also, the SKR can ask the TLV[4] to conduct HTA for medical devices to inform recommendations to regions on reimbursement.
• Healthcare professionals must work according to scientific knowledge and accepted standards of practice. • The government commissions Socialstyrelsen to provide evidence-based medical and long-term care guidelines. These guidelines are produced in collaboration with other actors, such as the SBU.	**Providers / professionals** Social-styrelsen[3]	**Purchasers / insurers** SKR[2]	• The 21 regions are responsible for financing, purchasing and delivering primary, specialist, and psychiatric health services. • 290 municipalities are responsible for care for the elderly and the disabled. • These authorities' decisions are guided by local priorities and national regulations. They are represented by the SKR.

1. The Swedish Agency for HTA and Assessment of Social Services 2. Swedish Association of Local Authorities and Regions 3. The National Board of Health and Welfare 4. The Dental and Pharmaceutical Benefits Agency (TLV) assesses and decides whether particular pharmaceutical products or dental care procedures should be covered.

Criteria in the decision-making process

Role HTA-body (SBU)

- The government mandates the SBU to review and evaluate healthcare technologies. Results are disseminated to central and local government officials and medical staff to provide basic data informing decision-making.
- The SBU does not give advice or recommendations.
- Socialstyrelsen can request that SBU perform HTA to establish the foundations for a guideline.

Criteria used by decision-making body (21 regions)

Depends on decisions made in each region according to their regional policy objectives

Inclusion and exclusion of care types

		Inclusion of care types	Exclusion of care types
Inpatient	Procedures	• Sweden has no nationally defined benefits package. • Sweden's 21 regions make independent decisions about treatment coverage and set provider fees at all care levels and co-payment rates for services such as primary-care visits and hospitalisations. • Although Socialstyrelsen sets national guidelines, regions are not obliged to follow them.	• Socialstyrelsen sets and reviews national guidelines every few years, updating them in line with any new available (scientific) evidence. • Socialstyrelsen also reviews and revises guidelines if it becomes aware of any new (scientific) evidence.
Inpatient	Medical devices		
Outpatient	Procedures	• The SKR's Medical Technology Council (MTC) identifies medical devices with a high budget impact or market power (or by regional request) and can ask TLV[1] to conduct HTA. Based on the result, the MTC recommends whether regions should reimburse a medical device and includes this in the guidelines. However, regions can still decide whether or not to reimburse certain medical devices.	
Outpatient	Medical devices		

Non-restrictive inclusion
Partially restrictive inclusion
Restrictive inclusion

1. The Dental and Pharmaceutical Benefits Agency

Germany

General overview of the healthcare system and its statutory healthcare package for curative care

Type of healthcare system

- The German healthcare system combines statutory health insurance (SHI) and private health insurance (PHI).
- Governance is decentralised and divided between the federal and state levels and corporatist bodies.[1]
- Those insured under SHI can choose between healthcare funds, while those insured under PHI can choose their private health insurer.
- Most providers serve both insured populations.
- The German system has no gatekeeping; patients have direct access to SHI-accredited in-and-outpatient healthcare.

Coverage[2]

- **Breadth**: Health insurance is compulsory for all residents, primarily supplied by SHI (for approximately 88% of the population in 2019).
- **Scope**: SHI covers a broad benefits package beyond essential services (e.g. treatment, prevention, health promotion, screening and transport).
- **Depth**: Medical and dental treatment is free at the point of use. For some health services, users are charged a co-payment.

Out-of-pocket (OOP) payments

- For some (supplementary) health services (e.g. hospital stays, medical aids and allied healthcare), patients must pay user charges. Children, pregnant women, people with substantial healthcare needs and those who are poor are exempt from co-payments.
- Co-payments are standardised at €10 per inpatient day (max. 28 days per year) and to 10% of ancillary outpatient services and products (min. €5, max. €10). User charges are capped annually at 2% of a person's household income, reduced to 1% for people with severe chronic illness.
- Out-of-pocket payments are relatively low, comprising only 14% of total health expenditures in 2017.

1. Corporatist bodies are primarily membership-based, self-regulated payer and provider organisations.
2. Breadth: *who* is covered. Scope: *what* is covered. Depth: *how much* is covered.

Main actors concerned with public curative-care coverage

• The G-BA is the decision-making body determining the benefits package under the Federal Ministry of Health's statutory supervision. • The G-BA comprises three neutral[4] members/representatives from the Federal Associations of providers, professionals and sickness funds and accredited patient organisations. • The G-BA evaluates treatments' relative value based on HTA-results to decide reimbursement.	**Decision-making body** G-BA[1]	**HTA-body** IQWiG[2]	• The G-BA often tasks the IQWiG with HTA. • The G-BA can also conduct HTA independently (e.g. for allied healthcare). • The IQWiG's objective is to provide HTA results informing the G-BA; it does not give advice or recommendations.
• Representatives of the Federal Association of SHI Physicians[5], German Hospital Federation[6], Federal Association of SHI Dentists[7] and accredited patient organisations participate in the G-BA evaluation and can propose treatments for evaluation.	**Providers / professionals** KBV[5], DKG[6], KZBV[7]	**Purchasers / insurers** GKV-Spitzen-verband[3]	• Sickness funds act as main payer institutions and are represented at the federal level by the GKV-Spitzenverband. • The GKV participates in the G-BA for evaluation and can propose treatments for evaluation. • The GKV also regulates and decides on high-risk medical aids' inclusion in the Catalogue of Medical Aids, which is necessary for SHI reimbursement.

1. Gemeinsamer Bundesausschuss (Federal Joint Committee) 2. Institut für Qualität und Wirtschaftlichkeit im Gesundheitswesen 3. Spitzenverband Bund der Krankenkassen 4. Providers and payers' associations choose one 'neutral' member each; these members should act impartially. The third member is the chairman. 5. Kassenärztliche Bundesvereinigung 6. Deutsche Krankenhausgesellschaft 7. Kassenzahnärztliche Bundesvereinigung

Criteria in the decision-making process

Role HTA-body (IQWiG)	Criteria used by decision-making body (G-BA)	
• The G-BA can task the IQWiG to conduct HTA. • The G-BA can also conduct HTA independently (e.g. for allied healthcare). • The IQWiG provides information to the G-BA to inform decision-making; it does not give advice or recommendations.	**Medical necessity**	Services must be medically necessary to qualify for reimbursement, i.e. deemed essential to the patient's health based on established medical knowledge, clinical guidelines and individual patient needs.
	Efficacy	Services must demonstrate proven effectiveness in achieving the intended patient health outcomes. This criterion is assessed based on scientific evidence, e.g. clinical trials, systematic reviews and healthcare professionals' expert opinions.
	Cost-effectiveness	Services must be cost-effective, i.e. the benefits outweigh the costs. This criterion considers the service's cost-effectiveness relative to alternative treatment options and available healthcare resources.
	Quality	Services must meet established quality standards, including clinical guidelines, best practices and patient-safety measures. This criterion ensures high-quality services aligned with established care standards.
	Feasibility	Services' implementation must be practically feasible, accounting for factors such as available resources, infrastructure and healthcare providers' expertise.

Inclusion and exclusion of care types

		Inclusion of care types	Exclusion of care types
Inpatient	Procedures	• Treatments are reimbursed unless explicitly excluded by the G-BA. • interventions are only evaluated upon referral from G-BA members. The G-BA comprises three neutral members/representatives of federal associations of providers, professionals and sickness funds and accredited patient organisations.	• Existing treatments' reimbursement is not systematically or regularly re-evaluated in practice. • Once treatments flow in, they rarely flow out. • To date, only individual cases generating significant public debate have led to disinvestment. These cases focused primarily on problematic safety, quality or ethical issues, not cost-effectiveness.
Inpatient	Medical devices		
Outpatient	Procedures	• Treatments are only covered following the G-BA's approval. • The G-BA considers HTA results alongside other evidence, stakeholder input and legal requirements. • The G-BA should make reimbursement decisions within 18 months. If not, treatments are automatically included in the benefits package.	
Outpatient	Medical devices		

Non-restrictive inclusion
Partially restrictive inclusion
Restrictive inclusion

France

General overview of the healthcare system and its statutory healthcare package for curative care

Type of healthcare system

- Since 2000, France has had a universal health coverage system (PUMa[1]).
- Enrollment in the statutory health insurance (SHI) system is mandatory.
- The insurance system is funded primarily by payroll taxes, national income tax and tax levies on certain industries and products.
- Outpatient care providers are largely private, while inpatient care providers comprise public and private non-profit or for-profit hospitals.
- In 2020, 95% of the population had complementary insurance – predominantly through employers - to help with OOP costs and dental, hearing and vision care.

Coverage[2]

- **Breadth**: Coverage is compulsory and provided to all residents by statutory health insurance funds.
- **Scope**: Prescribed diagnostics, services (incl. allied healthcare), drugs, transport and most in-kind benefits are provided via in-and-outpatient care. SHI provides in-cash benefits for sickness, maternity/paternity leaves and incapacity.
- **Depth**: Coverage is generally not 100%. There are no deductibles but a degree of co-payment, coinsurance and balance billing[3]. Some subgroups (e.g. low health status) are exempt from cost-sharing.

Out-of-pocket (OOP) payments

- In 2019, total OOP spending comprised 9% of total health expenditures.
- Co-payments for primary care and specialist consultation are no more than a few euros. A co-payment of €18 per day for hospitalisation is charged (up to 31 days).
- Most OOP spending is for dental and vision services, despite low co-payments. Providers commonly use balance billing for these services at over ten times the official fee. However, OOP spending for dental and vision services has been decreasing.

1. Protection Universelle Maladie 2. Breadth: who is covered. Scope: what is covered. Depth: how much is covered. 3. Some physicians are allowed to use balance billing above the national fee schedule (authorisation is based upon the duration of their hospital residency.)

Main actors concerned with public curative-care coverage

• The Ministry of Health and Prevention sets the national health strategy and allocates budgeted expenditures among different sectors and regions. • For medical devices the Ministry defines the benefits covered under SHI, while the National Health Insurance Fund (CNAM) decides on procedures. • The pricing committee (CEPS[5]) negotiates prices for medical devices[6] once coverage is decided.	**Decision-making body** Ministère de la Santé et de la Prevention	**HTA-body** HAS[1]	• The HAS is the main HTA body. The HAS is a public body that independently assesses technologies, hospitals, professionals and the basic benefit package. HAS gives advice and makes recommendations to the ministry and CEPS. • The government and SHI define HTA's governance and organisation.
• Associations of specialist physicians are responsible for supervising practice and developing guidelines. • The UNCPS represents healthcare professionals in private practice and is the single organisation that can negotiate with CNAM. • The Union of Practitioners in Public Hospitals SPHP represents physicians working in public practice.	**Providers / professionals** UNCPS[3], SPHP[4]	**Purchasers / insurers** CNAM[2]	• The CNAM represents SHI funds in negotiations with the state and healthcare providers.

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1. Haute Autorité de Santé 2. Caisse Nationale de l'Assurance Maladie 3. Union Nationale des Professionnels de Santé 4. Syndicat des Praticiens des Hôpitaux Publics 5. Comité Économique des Produits de Santé 6. All outpatient medical devices and inpatient medical devices financed through add-on payment.

Criteria in the decision-making process

Role of the HTA-body (HAS)

- HAS is tasked with HTA, which determines reimbursement rates and price negotiations.
- Since 2013, economic evaluation has been part of (re)assessment under certain circumstances. In practice, economic impact is not (yet) a key decision-making factor.
- HAS evaluation is mandatory for all interventions with (partially) restrictive inclusion.

Criteria used by the decision-making body (HAS)

Therapeutic value	• The severity and public health relevance of the disease under treatment, including epidemiological and quality-of-life aspects. • A treatment's medical benefit level (clinical efficacy and possible side-effects), evaluated in absolute terms for all use types. The assessment informs the reimbursement rate decision, ranging from 0% to 15%, 35%, 65% and 100%.
Comparative effectiveness	• A treatment's relative medical benefit compared to available treatments (The French ASMR scale ranks each drug compared to existing treatment options). • CEPS makes an explicit pricing decision according to the ASMR[1] rank. Manufacturers can negotiate a higher price for treatments ranked '1' to '4', incentivising them to provide sufficient data for assessment.
Economic impact	• The HAS Commission for Economic Evaluation and Public Health (CEESP[3]) will economically evaluate technology under assessment for the first time, potentially significantly impacting SHI expenditure. • In practice, economic impact is not (yet) a key factor in decision-making or price negotiations.

1. Amélioration du Service Médical Rendu 2. Rated on a scale from '1' for major improvement to '5' for no improvement 3. Commission d'Évaluation Économique et de Santé Publique

Inclusion and exclusion of care types

		Inclusion of care types	Exclusion of care types
Inpatient	Procedures	• Inpatient procedures can be provided and reimbursed unless excluded by the HAS. • Procedures related to the use of inpatient medical devices should be evaluated by HAS upfront and included in a positive list.	• Technologies are reassessed every five years based on the documents the manufacturer provides and systematic literature reviews.
Inpatient	Medical devices	• Only invasive (and expensive) devices and implants in the inpatient sector should be included in the LPPRs [1] 'liste en sus' (additional list). • All outpatient medical devices should be included in the LPPR or receive a positive HAS recommendation for innovation funding (for early access)[2]. • Interventions HAS deemed less effective are partially reimbursed (15%, 35% or 65%) through SHI. • In practice, treatments are often fully reimbursed through alternative means (see below). As a result, the inclusion is less restrictive than it appears (in which case we categorise the inclusion as 'partially restrictive'). • Complementary health insurance (95% of the population) covers the remaining amount and any co-payments. • For 30 chronic conditions (e.g. cancer and diabetes), the Ministry established the 'liste ALD[3]', for which related healthcare is fully reimbursed for everyone.	
Outpatient	Procedures		
Outpatient	Medical devices		

Non-restrictive inclusion
Partially restrictive inclusion
Restrictive inclusion

1. Liste de Produits et Prestation Remboursable 2. Forfait Innovation 3. La liste des Affections de Longue Durée

England

General overview of the healthcare system and its statutory healthcare package for curative care

Type of healthcare system

- All residents are automatically entitled to free public healthcare through the NHS[1], including hospital, physician and mental healthcare.
- The NHS budget is primarily funded through general taxation. A smaller proportion (20%) comes from national insurance (payroll tax).
- A government agency, NHS England, oversees and allocates funds to 42 ICSs[2], which govern and pay for care delivery at the local level. The government owns the hospitals and NHS care providers (NHS Trusts).
- In 2022, approx. 11% of the population had voluntary supplemental insurance for more rapid access to elective care.

Coverage[3]

- **Breadth**: Healthcare is accessible to all residents based on clinical need, regardless of their ability to pay.
- **Scope**: The NHS does not have an explicit list of benefits. Instead, the legislation outlines broad service categories that should be covered, e.g. in-and-outpatient care, maternity care, mental healthcare, medical devices and physician services. Service volume and scope are generally locally decided by ICSs. Some benefits are explicitly excluded (e.g. dental care and optometry).
- **Depth**: NHS care is mostly free at the point of use, though patients must make co-payments in some cases.

Out-of-pocket (OOP) payments

- Dentistry services are subject to co-payments of up to €290 per treatment course. Basis ophthalmic services are generally not covered under the NHS and require direct patient payments.
- Some populations, such as those under 16, over 60, on a low income or pregnant, are exempt from these user chargers.
- In total, OOP payments account for 17% of health expenditures, of which the largest component is long-term care (2022).

1. National Health Service 2. Integrated Care Systems (ICSs replaced the Clinical Commissioning Groups in 2022). ICSs are organisational partnerships that jointly plan and pay for regional healthcare services. 3. Breadth: *who* is covered. Scope: *what* is covered. Depth: *how much* is covered.

Main actors concerned with public curative-care coverage

• The responsibility for health legislation and general policy rests with Parliament, the Secretary for Health and the Department of Health. • Day-to-day responsibility lies with NHS England, an arm's length government-funded body run separately from the Department of Health. It manages the NHS budget, oversees the ICSs, and directly commissions certain types of care (e.g. public health services).	**Decision-making body** NHS England	**HTA-body** NICE[1]	• **NICE** provides national guidance (including clinical guidelines and HTA) on allocating resources most efficiently. • There are also NHS programmes to address unwarranted clinical variation and reduce the provision of low-value care, e.g. the Getting it Right the First Time (GIRFT) programme and the Evidence-Based Interventions (EBI) programme.[3]
• The government owns all NHS hospitals and providers, including ambulance and mental health services, district nursing and other community services. These providers are called NHS Trusts. • Healthcare providers procure medical devices and aids through the centralised NHS Supply Chain Service.	**Providers / professionals** NHS Trusts	**Purchasers / insurers** ICB[2]	• Through delegations, each ICS's Integrated Care Board (ICB) decides which treatments to fund when commissioning and delivering services.

1. National Institute for Health and Care Excellence 2. Integrated Care Boards 3. The NHS initiated the EBI programme in 2018 but recently discontinued it due to a lack of demonstrable impact.

Criteria in the decision-making process

Role of the HTA-body (NICE)	Criteria used by the decision-making body (NICE)	
• NICE provides national guidance on how to allocate resources most efficiently. • Adopting NICE's health technology appraisals is the only mandatory requirement: these are incorporated into NHS standard contracts and allocated funding. Adopting other NICE guidelines is not mandatory. • The Department of Health and Social Care decides the new technology appraisals or guidance NICE should develop.	**Incremental Cost-Effectiveness Ratio (ICER)**	• The central feature of NICE's approach to appraising treatments is comparing the incremental cost per QALY gained (over and above the current standard of care) with a decision-making threshold currently set between €25,000 and €35,000 per QALY (2021). • The QALY is intended to provide a generic measure of health gain and combines data on the extension and quality of life. • The decision-making threshold represents the opportunity cost of the current NHS budget constraint. However, there are several additional circumstances under which this threshold changes, e.g. for therapies that offer 3+ months additional life expectancy for patients with less than 24 months to live. In practice, this has resulted in NICE valuing QALYs at end-of-life at 2.5 times 'standard' QALYs (implying a decision-making threshold of €55,000 per QALY).

Inclusion and exclusion of care types

		Inclusion of care types	Exclusion of care types
Inpatient	Medical devices	• While medical devices must be registered with the MHRA[1], it is not compulsory that NICE assesses them. Manufacturers can voluntarily ask for a NICE recommendation if their device can be shown to reduce NHS costs.	• The remit of NICE also extends to pre-existing technologies through its clinical guidelines programmes, which explicitly consider costs through a systematic review of economic evaluation literature and identify candidates for disinvestment. • However, unlike the technology appraisal programmes, adoption of guideline recommendations is not mandatory for the NHS.
Inpatient	Procedures	• For novel interventions, NICE conducts HTA and has several guidance programmes. Almost all programmes consider clinical *and* cost-effectiveness (based on the ICER decision-making threshold). • Only procedures with a positive NICE technology appraisal, are incorporated into NHS standard contracts (and receive funding).	
Outpatient	Procedures		
Outpatient	Medical devices	• Medical devices must be registered with the MHRA[1], but it is not compulsory that NICE assesses them. Manufacturers can voluntarily ask for a NICE recommendation if their device can be shown to reduce NHS costs.	

SiRM. Strategies in Regulated Markets

Non-restrictive inclusion
Partially restrictive inclusion
Restrictive inclusion

1. Medicines and Healthcare Products Regulatory Agency. The MHRA is responsible for assessing the safety of novel medical devices and post-market surveillance.

Belgium

General overview of the healthcare system and its statutory healthcare package for curative care

Type of healthcare system

- The Belgian healthcare system is based on compulsory health insurance primarily financed by social contributions proportional to income.
- The organisation is divided between the Federal State[1] and the Federated entities[2]. The Federal State determines the 'index mass' (i.e. budget) each year.
- Care provision is based on the principles of independent medical practice, direct access, free choice and (predominantly) fee-for-service payment.
- Reimbursed healthcare services are provided by both public and private institutions and individual providers.
- Providers can choose whether or not to respect the negotiated national tariffs.[3]

Coverage[4]

- **Breadth**: Compulsory health insurance covers 99% of the population.
- **Scope**: The nationally established fee schedule (called the 'nomenclature') details and defines all reimbursed services. Representatives of the sickness funds and healthcare providers negotiate service tariffs annually or biennially.
- **Depth**: The extent to which OOP payments finance different health services indicates the main gaps in coverage. Also, when providers choose not to respect the negotiated national tariffs, patients must pay the difference OOP[5].

Out-of-pocket (OOP) payments

- OOP payments comprised 18% of total health expenditures in 2019 and are charged for non-reimbursed services, official co-payments and extra billings.
- Co-payments vary from service to service and by whether patients have preferential reimbursement status (e.g. people with preferential status pay €3 for a specialist medical consultation, while those without pay €12).
- Co-payments are either a fixed amount or a proportion of the official fee (or equal to zero). There is an annual cap on co-payments for people on low incomes.
- In 2019, OOP payments comprised 30% inpatient care, 30% outpatient care, 22% pharmaceutical, 12% dental care, 1% long-term care and 6% 'other' care.

1. Regulates the compulsory health insurance, hospital budget, etc. 2. Elderly and disabled care, mental healthcare, home care, rehabilitation and prevention. 3. Respecting negotiated tariffs offer benefits, e.g. higher pension contributions. When not respecting the national tariffs, the reimbursement amount for providers may be reduced by RIZIV. 4. Breadth: *who* is covered. Scope: *what* is covered. Depth: *how much* is covered. 5. This may interest patients because these providers usually offer faster access.

Main actors concerned with public curative-care coverage

• The RIZIV manages compulsory health insurance, while the Ministry of Health is responsible for the health system's general organisation and planning rules. • The RIZIV submits and assesses agreements between sickness-fund and healthcare-provider representatives (agreement committees) on service reimbursements.	 **Decision-making body** RIZIV[1]	 **HTA-body** KCE[2]	• The KCE provides independent scientific support to healthcare decision-makers. The KCE conducts HTA, clinical practice analyses and clinical guideline development. • Any individual, organisation or policy maker can submit topic proposals for assessment. From these, the KCE determines which topics to assess.
• Healthcare providers engage in decisions on tariffs and reimbursement of services via national conventions and agreements between providers' and sickness funds' representatives.	 **Providers / professionals**	 **Purchasers / insurers** Sickness funds	• Sickness funds are non-profit private organisations that operate i.a. the reimbursement system. • The health insurance budget relies on negotiations between government representatives, patients (via sickness funds), employers, employees and the self-employed. • The National Associations of Sickness Funds and the governmental body Supervising Authority of Sickness Funds (CDZ) exercise general control of those actors.

1. Rijksinstituut voor Ziekte- en Invaliditeitsverzekering /National Institute for Health and Disability Insurance 2. Federaal Kenniscentrum voor de Gezondheidszorg

Criteria in the decision-making process

Role of the HTA-body (KCE)

- The KCE conducts HTA, appealing annually to all stakeholders (providers, sickness funds, ministers, etc.) and deciding what topics to assess.
- KCE provides advice and recommendations but is not explicitly involved in reimbursement decision-making.
- The RIZIV also has its own committee for medical devices/implant HTA.

Criteria used by the decision-making body (RIZIV councils)

Information unknown

Inclusion and exclusion of care types

		Inclusion of care types	Exclusion of care types
Inpatient	Procedures	• The national fee schedule details all reimbursed services, specifying the official fees and cost-sharing mechanisms determined via annual or biennial conventions and agreements between representatives of sickness funds and healthcare providers. • Conventions are similar to agreements but cover lump sum payments for multidisciplinary care (e.g. rehabilitation or diabetes care).[1] • Sickness funds, health care providers and the minister can propose new treatments for uptake. • The technical councils and the committee concerning implants and invasive medical devices within the RIZIV formulate proposals to amend the national fee schedule. The RIZIV insurance committee (consisting of representatives of sickness funds and healthcare providers) approves the agreements and conventions.	• The RIZIV aims to promote (cost)effective care with the Appropriate Care Project. The aim is to save €40 million by reviewing (the indications for) treatments within the national fee schedule.
	Medical devices		
Outpatient	Procedures		
	Medical devices		

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Non-restrictive inclusion
Partially restrictive inclusion
Restrictive inclusion

1. Agreements made in the conventions are included in the so-called pseudo nomenclature (additional fee schedule). Volume restrictions and evaluation indicators with mandatory registration can be established. This is not possible for performances in the national fee schedule (the 'nomenclature').

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