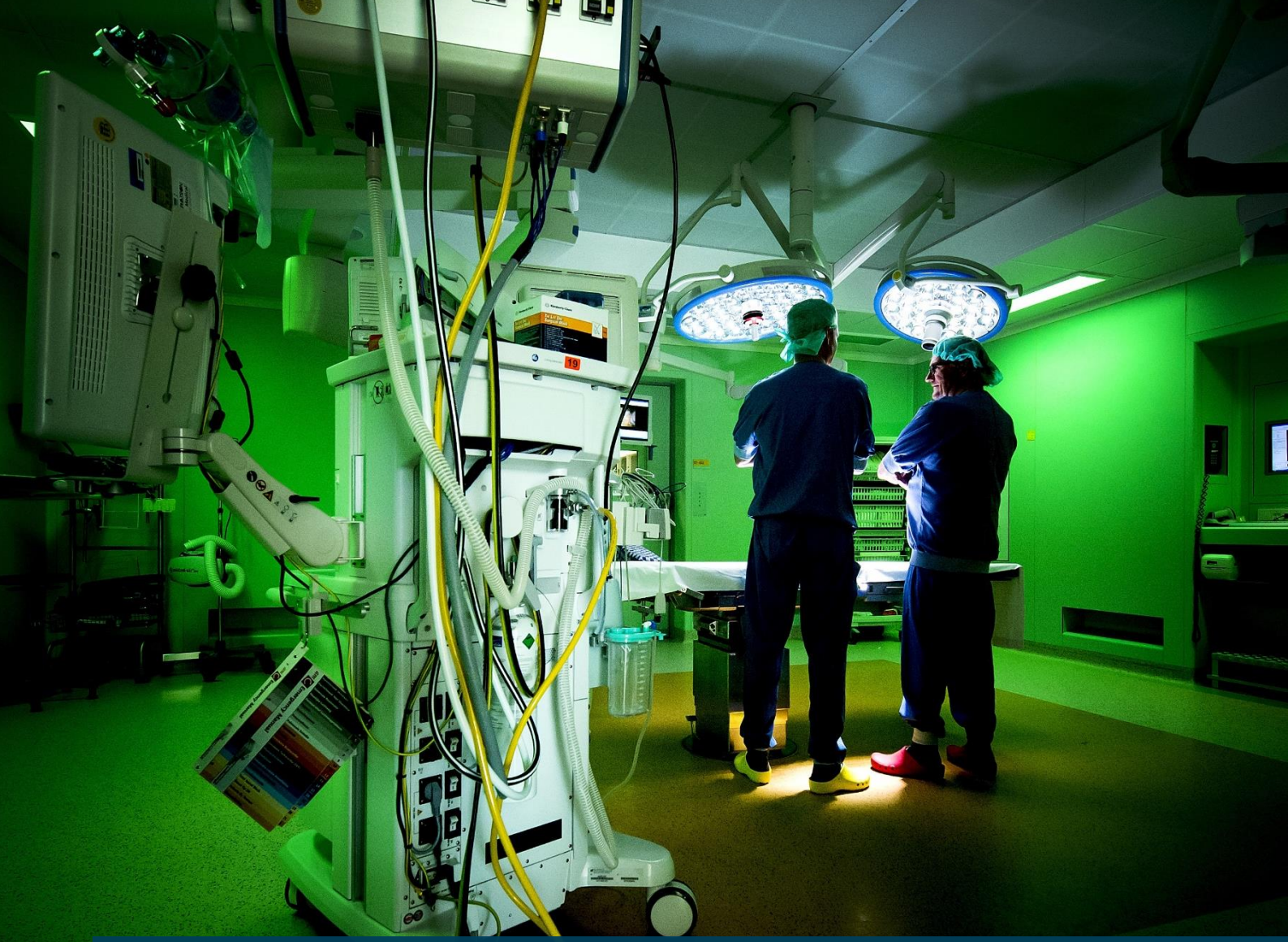

The grass is not greener

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

September 2023

SiRM. Strategies in Regulated Markets

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Executive summary

In the government's response to the Scientific Council for Government Policy's (WRR's) 'Choosing sustainable care' report, the ministers for Health, Welfare and Sport (VWS) and Finance established a technical working group to examine options for optimising macro-level healthcare spending. Among other things, this working group is investigating whether more government control over the content of the basic statutory healthcare package by assessment-based inclusion of all new treatments and care types, can improve control of collective healthcare spending. Currently, aside from outpatient care, expensive inpatient medicines and physiotherapy, the Netherlands' predominantly *non-restrictive* basic healthcare package automatically includes new treatments and care types. The Ministry of VWS's Macroeconomic Issues and Labour Market Directorate (MEVA) directorate asked SiRM to examine restrictive healthcare systems operating in Western European countries and the concomitant possibilities for controlling macro healthcare expenditure, particularly curative care. Based on extensive desk research and 25 interviews with experts from the comparison countries, we conclude that 'the grass is not greener' in Belgium, Germany, England, France or Sweden than in the Netherlands.

First, a wholly and definitively 'restrictive' basic healthcare package does not exist. How and to what extent a healthcare package is 'restrictive' varies across countries and care types. Moreover, 'restrictiveness' may reflect a system's focus on removing existing treatment or care types from the basic healthcare package. A system that gives more attention to care reassessment to determine its continued inclusion or subsequent exclusion is de facto more 'restrictive'. Furthermore, the role of effectiveness assessments in determining the inclusion or exclusion of care types from the basic healthcare package differs between countries. In the Netherlands, the Dutch Health Care Institute's effectiveness evaluations officially inform such decisions about inclusions and exclusions from the healthcare package. Thus, a care type that receives a negative assessment is removed from the basic healthcare package without the Ministry of Health's intervention, giving the Health Care Institute considerable power compared to other countries and a more restrictive package than its open entry suggests. How much care is still available *outside* the basic healthcare package also varies. In France, population-wide complementary insurance reimburses care types not fully covered by the statutory healthcare package.

Second, more restrictive packages do not imply lower curative-care spending. Our results show no association between a country's reimbursement of 34 examined treatments/devices and its basic healthcare package's restrictiveness, with other countries generally reimbursing the same care types as the Netherlands. However, countries with more 'restrictive' systems reimburse care types not reimbursed in the Netherlands and often reimburse more care in practice than their coverage regulations indicate due to culture, politics or monitoring difficulties of individual care. Moreover, curative care expenditures in the Netherlands are the lowest among all the countries examined despite its relatively non-restrictive healthcare package.

Despite its non-restrictive package, current Dutch initiatives appear to be at the forefront of basic healthcare regulation. However, national price negotiations in France offer an interesting option, particularly for extramural medical devices. Whether or not this approach suits the Dutch context warrants further investigation.

SiRM.

Content

1. Study objective and conclusion

1.1 Context and study objective

In the cabinet response to the Scientific Council for Government Policy (WRR)'s report 'Sustainable healthcare, a matter of choice: People, resources, and public support', the Health, Welfare and Sport (VWS) and Finance ministers established the technical working group overseeing healthcare spending.[1] This working group examines implementation strategies to improve the overall sustainability of Dutch healthcare spending. One such strategy relates to regulating the Netherlands' basic statutory healthcare package, involving greater government control of its content. Assessment-based inclusion of all new treatments and care types would be the most extreme form of such control.

The Netherlands' basic statutory healthcare package automatically includes all treatments and medical devices. Unlike new (expensive) medicines, new treatments are not routinely required to demonstrate cost-effectiveness for inclusion in insured service provision. We use the term 'non-restrictive' to describe this in the report. However, the Dutch Health Care Institute (Zorginstituut Nederland) may reassess any existing service and formally decide whether to continue or discontinue its inclusion in the package.

Given the rapid technological advancements in medical devices and e-health, the WRR expects the continued automatic inclusion of new treatments in the basic healthcare package will be unsustainable in the Netherlands. Therefore, it recommends tightening the regulation of the basic healthcare package to require proven cost-effectiveness for all the care types/treatments included, not just drugs.[2] Such a shift would lead to a more 'restrictive' entry of care and treatment types into the package.

The Ministry of VWS's Macroeconomic Issues and Labour Market Directorate (MEVA) commissioned SiRM to identify the types of 'restrictive' basic healthcare packages operating in other Western European countries and their possibilities for sustainable healthcare expenditure. More specifically, the MEVA directorate asked SiRM to examine the statutory regulations defining the basic healthcare packages in five Western European countries (Belgium, Germany, England, France and Sweden), focusing particularly on curative care[3] but excluding medicines and

[1] Minister van Volksgezondheid, Welzijn en Sport, Kamerbrief 'Technische werkgroep macrobeheersing zorguitgaven', 29 september 2022.
[2] The WRR notes that assessing all new treatments and interventions as thoroughly as drugs is unfeasible but that a broader scope is desirable. It indicates that there are still several practical barriers to this, such as only one party responsible for demonstrating (cost)-effectiveness and thus having the incentive to supply the necessary information or an insufficient knowledge base to assess the effectiveness of interventions.
[3] In consultation with the technical working group and the guidance committee, SiRM limited this study's scope to curative care. This is because more knowledge is required on the (cost)-effectiveness of treatments and/or medical devices in long-term care in all the countries studied. Whether treatments and/or medical devices in long-term care are collectively reimbursed relates more to cultural-social considerations than package decisions. This makes other aspects of regulating the health care package (as included in the report 'Pakketbeheer in de Praktijk 4' by the National Health Care Institute) more important, such as proactive and risk-oriented identification and prioritisation of care.

physiotherapy. This report uses the term 'basic healthcare package' (abbreviated to 'package') to mean the healthcare benefits a country statutorily funds and provides, i.e. the package of healthcare treatments and care types approved for reimbursement by the national healthcare system and/or mandatory health insurance. We do not use this term to mean private healthcare packages.

Although we included Sweden in this report's appendices, we chose not to include it in the concluding chapters (Chapters 2 and 3). This is because Sweden's system is primarily 'non-restrictive', automatically including all treatments in its basic healthcare package. Thus, there is less to learn from this country about 'restrictive' systems. Moreover, Sweden's healthcare provision is regionally rather than nationally defined. Since regions independently decide their population's healthcare provision, Swedish healthcare reimbursement varies from region to region.

1.2 Conclusion

Based on extensive desk research and 25 interviews with experts from comparison countries, we conclude that 'the grass is not greener' in Belgium, Germany, England, France or Sweden than in the Netherlands.

First, no definitively 'restrictive' healthcare system exists (Chapter 2). How and to what extent a country's basic healthcare package limits reimbursed treatments varies by country and care type. A package's 'restrictiveness' may also reflect the system's focus on reassessing existing care types to decide whether to continue or discontinue their inclusion in the basic healthcare package, i.e. excluding those without proven cost-effectiveness. Moreover, effectiveness assessments play different roles in defining included and excluded treatment types. Finally, the extent to which treatments outside a 'restrictive' system are still available, varies.

Second, the 'restrictiveness' of a country's basic healthcare package does not correlate with lower curative-care spending in our analyses (Chapter 3). Our results show no clear relationship between a country's reimbursement practices for 34 examined treatments and its healthcare package's 'restrictiveness'. Moreover, the comparison countries reimburse more care in practice than expected for a restrictive system due to factors such as culture, politics or the difficulty of monitoring national control over individual care. Finally, despite its relatively non-restrictive health provision, the Netherlands' curative-care expenditure is the lowest among all the countries examined.

Reflecting on the Dutch system, we note that the Netherlands appears to be a frontrunner with it's current initiatieves by the Ministry of Health, the National Health Care Institute, and the Health Care Evaluation and Appropriate Use (ZE&GG[4]) programme (Chapter 4). However, the national price negotiations in France for (particularly) outpatient medical devices offer an interesting policy option for the Netherlands. Whether this is also applicable in the Dutch context warrants further investigation.

[4] In Dutch: Zorgevaluatie en Gepast Gebruik

2. No definitively 'restrictive' basic healthcare package exists

A definitively 'restrictive' basic healthcare package does not exist. The type and level of a basic healthcare package's restrictiveness varies by country and care type, with outpatient care more often restricted than inpatient care (§2.1). Moreover, the focus on re-evaluating currently included treatments for possible exclusion differs across countries (§2.2), as does the role of effectiveness assessments in deciding a treatment's inclusion and exclusion (§2.3). Finally, the extent to which care outside the basic healthcare package remains available also differs (§2.4).

This chapter argues that a definitively 'restrictive' basic curative-care healthcare package does not exist.[5] There is no universally accepted definition or example as far as we know. Therefore, we distinguish four aspects affecting a system's level of restrictiveness:

1. Whether the basic healthcare package automatically includes new treatments without an official regulatory body's explicit decision (§2.1).
2. Whether previously included treatments are subject to reassessment and possible subsequent exclusion, e.g. because they are obsolete or no longer cost-effective (§2.2).
3. The role of effectiveness assessments in determining a treatment's inclusion or exclusion (§2.3).
4. The extent to which treatments outside the basic healthcare package are still reimbursed (§2.4).

We compared the regulation of the statutory healthcare package in the Netherlands with that in four other countries: Belgium, Germany, England and France. All four show some degree of restrictiveness. Appendix 4 details each country's treatment regulation and reimbursement practices within the broader context of its national healthcare system.

2.1 The restrictiveness of a country's basic healthcare package differs by care type

Three of the countries examined (Germany, France and England) only restrict incoming treatments for a subset of curative care[6] (§2.1.1). Only Belgium restricts new treatments for all care types (§2.1.2). The Netherlands automatically includes treatments for all care types,[5] although the Ministry of VWS can set conditions for specific medical procedures based on the Special Medical

[5] We did not include (expensive) medicines and physiotherapy in this study's scope.
[6] Unless otherwise stated, any reference to 'care' in this report means curative care.

Operations Act. For example, the VWS Minister capped the number of centres performing proton therapy at three in 2013.[7]

2.1.1 Germany, France and England have partially restrictive systems depending on the care type

Germany's system is only restrictive for non-hospital care

Germany's system only restricts outpatient treatment[8] and medical devices, automatically covering all inpatient care.

Therefore, German sickness funds only reimburse non-hospital care subject to the Federal Joint Committee's (Gemeinsamer Bundesausschuss [G-BA]'s) authorisation. The federal committee comprises 13 members: five sickness-fund representatives, five healthcare-provider representatives, two neutral members[9] and an impartial chairman. Patient representatives on the G-BA can give advice or submit applications but do not have the right to vote on care reimbursement. Medical device manufacturers can also apply for an evaluation/assessment alongside G-BA members.[10]

Relevant parties (such as trade associations of the representative umbrella organisations participating in the G-BA and medical device manufacturers) can also submit comments orally and in writing before the G-BA's final decision.[11] The Ministry of Health has the right to raise objections within two months post-publication.[12]

France restricts the inclusion of new outpatient care and invasive medical device/implants in inpatient care

Like Germany, France restricts the inclusion of all new outpatient treatments and medical devices and invasive and/or expensive (and high-risk)[13] medical devices and implants in inpatient care. However, its basic healthcare package automatically includes all other inpatient care.

The National Health Authority (Haute Autorité de Santé [HAS]) is an independent public body whose government-appointed board is authorised to assess treatments and issue recommendations for their inclusion in (or exclusion from) the basic healthcare package. Two committees play an essential role:

[7] Aanhangsel Handelingen (Appendix to Acts of Parliament), session 2021-2022, no 3667.
[8] Unless otherwise specified, we use the term 'treatments' to mean both diagnostic and therapeutic procedures.
[9] The representatives of sickness funds and healthcare providers each elect one neutral member. In principle, these two delegates should be impartial.
[10] Gemeinsamer Bundesausschuss, Bewertung neuer Untersuchungs- und Behandlungsmethoden für die ambulante und/oder stationäre Versorgung (accessed 26 June 2023).
[11] Gemeinsamer Bundesausschuss, Stellungnahmeberechtigte (2023).
[12] Verfahrensordnung des Gemeinsamen Bundesausschusses (2022).
[13] However, assessing high-risk inpatient devices is only about safety, not (cost-)effectiveness. After a positive assessment, the device is included in la liste positive intra Groupes Homogènes de Séjours (GHS).

- The Commission Nationale d'Évaluation des Dispositifs Médicaux et des Technologies de Santé (CNEDIMTS), which assesses therapeutic procedures and medical devices and technologies.[14]
- The Commission d'Évaluation des Technologies de Santé Diagnostiques, Pronostiques et Prédictives (CEDiag),[15] which assesses diagnostic and prognostic interventions since 2023.

The CNEDIMTS advices the Ministry of Health and Prevention on reimbursement decisions for medical devices. However, the final decision lies with the Minister. For procedures (and medical devices in an early access procedure) the board of the HAS gives the final advice to the ministry. Both committees comprise approximately 20 voting members, primarily healthcare professionals but some patient representatives. Representatives of various ministries and health insurers sit on both committees as advisory members. Since 2015, HAS can ask other relevant parties, such as manufacturers, to respond on its assessments and decisions that are relevant to them.

England is partially restrictive for new inpatient and outpatient treatments

England's basic healthcare package is partially restrictive for inpatient and outpatient treatments but automatically includes medical devices. However, manufacturers of medical devices can request an assessment by the National Institute for Health and Care Excellence (NICE). Also other organisations, such as NHS England of organisations performing horizon scanning, can suggest medical devices for assessment.

Treatments are only included in statutory healthcare provisions after a positive recommendation in NICE guidance. NICE is an independent public organisation whose board comprises a chairperson, eight non-executive members (supervisory members) and four executive directors, all appointed by the Secretary of State for Health and Social Care.[16] The Ministry[17] determines which treatments NICE produces guidance for. According to interviewees, the agenda-setting process for choosing treatments for assessment is not entirely clear and transparent.

Several committees within NICE are responsible for drafting the various forms of guidance, including the 'NICE guidelines' and 'technology appraisals'. These committees primarily involve healthcare providers, purchasers, users and academics, sometimes supported by separate committees that carry out effectiveness assessments.[18] Although the Guidance Executive (comprising NICE directors) ultimately approves the guidance for publication,[19] direct stakeholders (such as professional associations) can comment on the draft guidance.

NICE produces seven types of guidance, including NICE guidelines, diagnostics guidance and technology appraisal guidance.[20] Of these, only technology appraisal guidance is formally linked

[14] Haute Autorité de Santé (2023). Commission nationale d'évaluation des dispositifs médicaux et des technologies de santé.
[15] Haute Autorité de Santé (2023). Commission d'évaluation des technologies de santé diagnostiques, pronostiques et prédictives.
[16] Department of Health (2015). Report of the triennial review of the National Institute for Health and Care Excellence.
[17] The Department of Health and Social Care.
[18] Such as Technology Appraisals, Diagnostics Guidance, Medical Technology Evaluations and Highly Specialised Technologies Evaluations.
[19] National Institute of Health and Care Excellence (2023). How we develop NICE guidelines.
[20] NICE is also developing a new approach to encourage more use of promising innovative treatments. In doing so, NICE is assessing early evidence to determine whether the innovation can conditionally enter the package earlier.

to reimbursement practices. The NHS is legally obliged to fund treatments with a positive technology appraisal and ensure their availability to patients within three months.[21]

2.1.2 Only Belgium's basic healthcare package is entirely restrictive for all care types

Belgium's basic healthcare package is restrictive for all in-and-outpatient treatments and medical devices. Statutory health insurance sickness funds only reimburse care included in a federal institution's 'nomenclature' (the Belgian/French name for the national fee schedule) under the Minister of Social Affairs' supervision: the National Institute for Health and Disability Insurance (Rijksinstituut voor Ziekte- en Invaliditeitsverzekering [RIZIV]). The national fee schedule is the official list of reimbursable diagnostic and therapeutic procedures. It describes all included services, including rates and conditions (such as indication criteria) for claiming a service, but does not set volume limits.

Sickness funds and healthcare providers propose changes to the national fee schedule and negotiate corresponding rates and co-payment levels within specific RIZIV councils. The RIZIV's General Council makes final decisions on which care is reimbursed and at what rate. Parties responsible for financing the insurance[22] have three-quarters of the mandate, and sickness funds the remainder. Healthcare providers only have an advisory voice, and patient representatives have no explicit role within the RIZIV's various councils.[23]

In addition, Belgium defines a specific addition to the national fee schedule called the 'pseudo-nomenclature'. Agreements between sickness funds and healthcare providers formalise arrangements about the multidisciplinary care (such as rehabilitation or diabetes care) to be reimbursed and the fixed amount sickness funds will pay. These agreements are known as 'conventions', the details of which are included in the pseudo-nomenclature and may include agreed volume restrictions. Sickness funds and healthcare providers can also agree on evaluation indicators with a possible registration obligation, allowing them to evaluate care and adjust the conventions if needed.[24]

2.2 A package's 'restrictiveness' might reflect its focus on evaluating and potentially excluding existing care

A basic healthcare package's 'restrictiveness' might also reflect whether the included treatments are subsequently re-evaluated. In this context, England, France and the Netherlands focus regulatory attention on reviewing currently included treatments, thereby deciding whether to retain or remove them from the package. However, realisation does not seem self-evident in

[21] National Institute of Health and Care Excellence, 2023. NICE Technology Appraisal Guidance.
[22] Employers, employees, self-employed and government representatives.
[23] Interviewees indicate that although patient organisations can advise, this happens very little in practice. They indicate that patient representation is mainly through sickness funds.
[24] Sickness funds automatically offer additionally insured services (such as orthodontics and glasses). The scope varies widely between sickness funds. Since 2012, enrolment for these additional services has been compulsory and insured people pay a collective premium. Residents who do not want this can choose to register with the Hulpkas voor Ziekte- en Invaliditeitsverzekering (HZIV) / Auxiliary Health and Disability Insurance Fund. This neutral public body only administers compulsory health insurance and does not insure supplementary services. Source: Health Systems in Transition, Vol. 22, No. 5 (2020). Health system review: Belgium.

practice (§2.2.1). Belgium and Germany focus less on regulating treatments/care types post-inclusion and are thus less restrictive in this respect (§2.2.2).

2.2.1 The Netherlands, England and France review existing care, although realisation is not obvious

The Netherlands' basic healthcare package is more restrictive than its non-exclusionary uptake of new treatments might suggest. This apparent contradiction is due to the Health Care Institute's capacity to subsequently exclude any automatically included care based on its assessment (see §1.1). Where the Health Care Institute's assessment of a treatment or care type is negative, they can remove it from the benefits package independently of the Ministry of VWS. In addition, national-level initiatives, such as the Care Evaluation & Appropriate Use (ZE&GG) programme, aim to remove non-effective care from the package. This ZE&GG programme runs until 2024 and focuses explicitly on the changes needed in healthcare providers' practice to remove non-effective care. Despite the programme's successes, it is not yet clear whether it will achieve its primary objectives.

NICE can reassess treatment or care types already included in statutory healthcare provision in England. It is unclear to what extent this happens structurally and the degree of subsequent treatment/care exclusion. NICE decides the schedule of reassessments, aiming to conduct them within three to six months of new evidence becoming available, although it is unclear how much this happens in practice. In addition, NICE identifies treatments for removal from the package based on insufficient cost-effectiveness when drafting or updating clinical guidelines. Although regional care purchasers must follow NICE's technology-appraisal recommendations, they are not obliged to follow their clinical guideline recommendations.

In 2018, NHS England and NICE collaborated to establish the Evidence-Based Interventions (EBI) Programme, similar to the Dutch ZE&GG programme. The EBI programme identified 4 treatments to completely phase out of the statutory healthcare package (such as knee arthroscopy for arthritis) and 13 treatments for provision only under strict conditions (such as breast reduction). NHS England discontinued the EBI programme after a few years because of insufficiently demonstrated impact.

In France, HAS reassesses medical devices included in statutory healthcare package every five years, applying the same criteria as the initial HAS review. HAS re-evaluates devices based on manufacturer-supplied documents and/or systematic literature reviews. However, interviewees indicated this happens less in practice than is structurally prescribed, partly due to HAS capacity shortages. HAS is also responsible for updating clinical guidelines based on new scientific evidence based on field evidence and scheduled reviews of new scientific literature.[25] How much this occurs in practice is unclear.[26]

[25] Haute Autorité de Santé (2023). Actualisation des recommandations de bonne pratique et des parcours de soins.
[26] Over the past five years, the CNEDIMTS reviewed about 60 medical devices per year for review of their inclusion in the LPPR and about 45 medical devices to review the conditions under which these devices are included in the LPPR.

2.2.2 Belgium and Germany focus less on re-evaluating and removing existing care

Belgium rarely removes non-(cost-)effective care from its statutory healthcare package, only excluding treatments when healthcare providers no longer (or rarely) declare them. In addition, the RIZIV set up the Appropriate Care Unit[27] initiative in 2016 to remove non-cost-effective care from its national fee schedule or prescribe stricter conditions. The initiative identified - among other things[28] - 40 million euros worth of non-cost-effective care, removing the benefits-in-kind from the national fee schedule or prescribing stricter conditions.[29] However, this generated considerable resistance among healthcare providers, resulting in the reversal of these removals. The RIZIV subsequently reduced reimbursements tariffs for these benefits-in-kind.

Similarly, very few treatment or care types exit Germany's basic healthcare package once included. Care is only removed if it becomes obsolete (e.g. when a device is no longer available on the market) or is found to be unsafe. Deciding to remove currently included care types is problematic because it requires at least 9 of the G-BA's 13 votes. This outcome is unlikely, given the G-BA's composition (see §2.1.1). In addition, interviewees report that decision-makers still feel little urgency to remove treatment or care types based on cost-effectiveness.

2.3 Effectiveness assessments play different roles in deciding a treatment's entry and/or exit from the healthcare package

Often referred to as Health Technology Assessments (HTAs), effectiveness assessments play different roles in determining a treatment's entry and/or exit from the basic healthcare package across the countries studied, playing a more formal role in the Netherlands, England and France (see §2.3.1) than in Belgium and Germany (see §2.3.2). Appendix 2 details the results of published effectiveness assessments in each focus country over the past 20 years, showing that the number and focus of each country's assessments differ.

2.3.1 The Netherlands, England and France formally use effectiveness assessments to decide on the entry and/or exit of treatment types from the basic healthcare package

In the Netherlands, the Health Care Institute's effectiveness assessments inform decisions about the basic healthcare package

The Dutch Health Care Institute can review and issue a position on care that has already entered[30] statutory healthcare based on at least two criteria[31]:

1 The 'State of Science and Practice' assessment framework: the 'State of Science and Practice' criteria define sufficient scientifically proven effectiveness. Only medical care that complies

[27] Also known as: Cel Doelmatige Zorg van Actieplan Handhaving (Cell for Efficient Care of Enforcement Action Plan).
[28] The Appropriate Care Unit also prepares budget neutral reforms to align existing regulations with international guidelines.
[29] For example, an age limit in fertility treatments.
[30] The Health Care Institute can also decide to issue a position before care enters, although this is less common.
[31] A third criterion that insured care must meet is the criterion of 'reasonably necessary.' This criterion is intended to determine in individual cases whether an insured person is genuinely in need of care as commonly provided by healthcare providers and that complies with the 'State of Science and Practice' (SW&P). This is the so-called indication requirement that the health insurer must assess.

with these criteria can be reimbursed under the basic healthcare package. Thus, medical care must meet these criteria to be eligible for inclusion in the package.[32]

2 'Current practice of care': the medical profession must count the care as acceptable and delivered professionally.

Health insurers, health care providers and/or any other parties (representative associations, the Ministry of VWS or the Health Care Institute itself) can request a positional review by the Health Care Institute.[33] The review's outcome is a formal decision on whether or not the care should remain in the statutory healthcare package, meaning that the Health Care Institute's position affects the package's scope without the Ministry of VWS's intervention. Care that receives a negative assessment is removed from the statutory healthcare package.

The Health Care Institute mainly issues positional reviews on care with a relatively small cost impact (Figure 1). Meanwhile, the Ministry of VWS and the Health Care Institute intend to reform healthcare package regulation to focus more on risk-oriented regulation.[34] For this purpose a societally relevant agenda-setting framework[35] has been developed (this is further explained in Chapter 4).

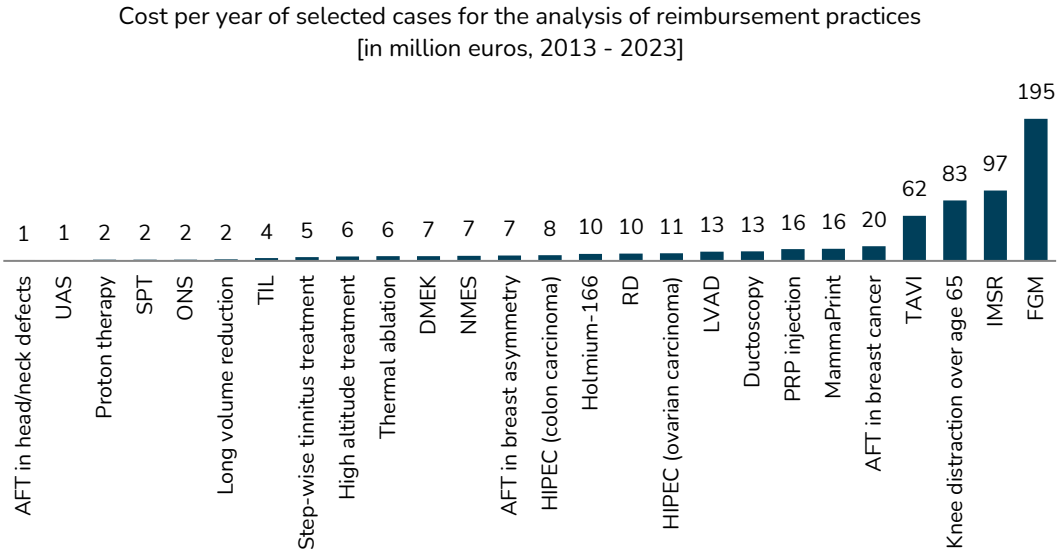

Figure 1. The Health Care Institute primarily issued positions with a relatively small cost impact over the past decade. Four selected positions have a cost impact of more than €60 million. The horizontal axis shows the treatment abbreviations. Full names are given in Appendix 3. Source: SiRM analysis.[36]

[32] For a complete description of this criterion, refer to the document 'Beoordeling Stand van de Wetenschap en Praktijk 2023' by the National Health Care Institute.

[33] Insured individuals can submit a 'dispute' with an insurer to the Foundation for Complaints and Disputes in Health Insurance (Stichting Klachten en Geschillen Zorgverzekeringen – SKGZ). The SKGZ can then decide to refer a dispute to the National Health Care Institute.

[34] Ministerie van Volksgezondheid, Welzijn en Sport, Kamerbrief: 'Verbeteren en verbreden van de toets op het basispakket', December 2, 2022. Rapport Zorginstituut Nederland: Pakketbeheer in de praktijk 4 (March 2023).

[35] Zorginstituut Nederland (2023). Pakketagenda passende zorg 2023 – 2025. See: https://www.zorginstituutnederland.nl/publicaties/publicatie/2023/07/18/pakketagenda-passende-zorg

[36] We have only included positions for which a cost attachment is included in the Care Institute's position.

In England, NICE explicitly tests treatments' clinical and cost-effectiveness

NICE assesses the clinical and cost-effectiveness of treatments in England[37] using an explicit decision threshold based on the Incremental Cost-Effectiveness Ratio (ICER).[38] It recommends effective treatments if they cost less than about €35.000 per Quality-Adjusted Life Year (QALY) gained compared to standard treatment.[39] NICE uses the ICER for the technology appraisal recommendations that regional healthcare purchasers must follow, formally linking package decisions to clinical and cost-effectiveness. NICE also uses the ICER as a decision threshold for other guidance recommendations, although healthcare purchasers are not obliged to follow these.

In France, the assessment of (relative) effectiveness of the Haute Autorité de Santé (HAS)[40] influences the reimbursement level and rate

France also links effectiveness assessments to statutory healthcare package decisions. HAS does this via two steps. First, it determines the reimbursement rate (0%, 15%, 35%, 65% or 100%) based on effectiveness. Second, it determines the treatment or device's relative effectiveness compared to existing care, scoring it according to five Amélioration du Service Médical Rendu (ASMR) levels. Based on this level, the French government negotiates the price with manufacturers or healthcare providers.[41] Thus, ASMR levels 1–4 permit manufacturers and healthcare providers to negotiate a higher price than the standard treatment. According to interviewees, this incentivises manufacturers and healthcare providers to supply sufficient data.

If necessary, HAS can also conduct an economic impact evaluation when (re)assessing medical devices with high relative effectiveness and a significant budget impact.[42] However, interviewees report that this is not yet a decisive decision-making issue.[43]

2.3.2 Belgium and Germany do not formally link effectiveness assessments to their basic healthcare package decisions

In Belgium, the Federal Health Care Knowledge Centre (KCE) conducts effectiveness assessments, annually appealing to all stakeholders for submissions before deciding which care to assess. The KCE then formulates recommendations to the National Institute for Health and Disability Insurance (RIZIV) or other parties, publishing them publicly. RIZIV also has an

[37] The single case where NICE assess clinical effectiveness only is the 'Interventional Procedures Programme'. These are diagnostic or therapeutic treatments in which, for example, a tube is inserted into a blood vessel through a bodily incision or an instrument is inserted through the mouth to treat the stomach.
[38] This threshold can change, e.g. for treatments adding more than three months of life expectancy for patients with no more than two years to live. In this case, NICE values the QALYs at 2.5 times the 'standard' QALY (implying a decision threshold of €55.000 per QALY).
[39] Health Systems in Transition, Vol. 24 No. 1 (2022). United Kingdom: health system review.
[40] HAS is an independent public organisation with a government-elected board. Haute Autorité de Santé (2023). Organisation de la HAS.
[41] The price of medical devices is centrally negotiated in France based on their expected effectiveness, similar to the Financial Arrangements Bureau for expensive drugs in the Netherlands. This is known as the Comité Economique des Produits de Santé (CEPS) in France and falls under the responsibility of the ministries of health, social affairs and economic affairs. Interviewees indicate that this is an effective system. It is currently beyond the scope of this assignment. Belgian healthcare providers and sickness funds also negotiate reimbursable rates within agreement committees and conventions. Although effectiveness assessments are informative here, they are not formally linked to tariff setting as in France.
[42] Or has (expected) sales of 20 million euros or more after two years on the market.
[43] Health Systems in Transition, Vol. 17 No. 3 (2015). France: Health system review.

independent committee that conducts effectiveness assessments for invasive medical devices and implants. RIZIV's various councils (see §2.1.2) are not obliged to use either the KCE or their own effectiveness assessments when making healthcare package decisions, and it is unclear how far they include them.

In Belgium, sickness funds are less incentivised to select included treatments based on cost-effectiveness because they do not compete for the statutory benefits packages in an open market, as in the Netherlands. Clinical and cost-effectiveness plays less of a role in the care-reimbursement decision-making process because, unlike in the Netherlands, sickness funds are limited risk-bearing. Like healthcare providers, they focus on expanding the healthcare package care available to those they insure.[44] Sickness funds compete based on their 'customer' service and their complementary insurance policies.

IQWiG conducts effectiveness assessments in Germany. IQWiG is an independent scientific institute the G-BA can commission to conduct effectiveness assessments for certain care types. Although IQWiG provides scientific reports, it does not provide positions or recommendations for statutory healthcare package decisions. The G-BA does usually follow the results of the assessments by IQWiG. However, IQWiG's assessments are not binding. The G-BA also has its own effectiveness assessment committees (e.g. for paramedical care),[45] although how much they use the results in decision-making is unclear.

2.4 To what extent care outside the statutory healthcare package is still reimbursed varies

2.4.1 France still reimburses a significant amount of care, despite its partially-restrictive basic healthcare package

Almost all care in France is still reimbursed, despite limiting the entry of new care types into the basic healthcare package and using assessment-led reimbursement rates. There are two primary reasons for this:

1. Approximately 95% of the French population have complementary insurance that covers the difference between HAS's reimbursement rate and the full rate.[46] HAS sets the reimbursement rate at 0%, 15%, 35%, 65% or 100% based on the effectiveness assessment. The complementary insurance mostly covers the difference when the reimbursement rate is lower than 100%.[47]

[44] In Belgium, the macro budget is set at the federal level based on trend analysis (including demographics) and an annual growth rate. The budget for compulsory health insurance is divided nationally between healthcare sectors. Negotiations are taking place in which a tariff agreement is concluded for each healthcare sector. During these negotiations, the health insurance funds can decide with the healthcare providers whether to include new benefits in the basic package or to adjust existing benefits (based on effectiveness assessments).
[45] Health Systems in Transition, Vol. 22 No. 6 (2020). Germany: Health system review.
[46] This group is mainly those with supplementary insurance through their employer (89% of the total population). The remaining 6% with supplementary insurance are low-income, receiving income-dependent vouchers. Supplementary insurance finances about 14% of total healthcare expenditure in France. Source: DREES, Les dépenses de santé en 2017.
[47] This is also known as 'balance billing'.

2 The French national health insurer fully reimburses all effective care for 30 chronic conditions (such as diabetes and Parkinson's) listed in the 'liste Affection Longue Durée' (ALD) for all residents.[48]

2.4.2 Accelerated reimbursement of specific treatments and/or medical devices is possible in Belgium, France and the Netherlands

Belgium, France and the Netherlands have separate options for reimbursing care outside the basic healthcare package for specific treatments and/or medical devices. In Belgium, for example, the RIZIV can enter into agreements with third parties via an Article 56 procedure to finance specific treatments and/or medical devices not included in the national fee schedule. This procedure allows conditional care reimbursement while gathering more evidence on effectiveness. Manufacturers, healthcare providers or patients can apply to the RIZIV for this dispensation. The treatment is temporarily reimbursed for two to three years (e.g. negative pressure wound therapy or next-generation sequencing for breast cancer). However, this does not guarantee permanent inclusion in the statutory healthcare package afterwards. An interviewee indicates that the extent of use of the Article 56 procedure amounts to an average of 60-70 million euros annually.

In France, innovative medical devices can also enter early through what is known as ‘Forfait Innovation’. Manufacturers can request a HAS assessment to qualify for the Forfait Innovation. Technology given a positive assessment is then conditionally reimbursed.[49]

Similar procedures also existed in the Netherlands before 2019, when conditional authorisation was largely replaced by the Promising Care Subsidy Scheme and a separate conditional authorisation procedure for expensive medicines (orphan drugs, conditionals and exceptionals). In this way, further research can be conducted to assess the effectiveness in support of a final decision on inclusion in the basic healthcare package. In 2022, eight medical studies received subsidies under the Promising Care Subsidy Scheme.

2.4.3 Belgium and England have separate possibilities for reimbursing individual patients for care outside the basic healthcare package

At the individual level, Belgium and England offer separate possibilities for reimbursing patients for specific care outside the basic healthcare package. For example, Belgium has the Special Solidarity Fund (BSF), which reimburses care for a life-threatening condition in exceptional cases when an expensive non-experimental therapy is necessary that is not covered by compulsory health insurance. Although the fund is relatively small and mainly reimburses (expensive) drugs, it still enables care reimbursement outside the basic healthcare package.[50] Similarly, doctors in England can request an Individual Funding Request (IFR) from NHS England for a patient in exceptional cases. If the IFR request is approved, the NHS still reimburses the patient’s treatment despite being outside the statutory healthcare package.

[48] L'Assurance Maladie (2023). Qu'est-ce que le dispositif appelé Affection Longue Durée (ALD)?
[49] Ministère de la Santé et de la Prevention. (2023). Forfait Innovation.
[50] The BSF had an annual budget of around €8 million in 2021. More than 80% of patients for whom care is funded are treated with (expensive) drugs.

3. Restrictiveness does not correlate with lower curative-care spending

A more restrictive basic healthcare package does not correlate with lower curative-care spending. We see no clear relationship between a country's reimbursement for 34 examined treatments and devices and its basic healthcare package's restrictiveness (§3.1). Comparison countries also reimburse more care in practice than we anticipated in theory, likely because of culture, politics or the difficulty of monitoring national control over individual care (§3.2). Moreover, curative-care expenditure is lower in the Netherlands than in comparison countries despite its relatively non-restrictive package (§3.3).

This chapter argues that a more restrictive basic healthcare package does not lead to lower curative-care spending. To show this, we first ranked the comparison countries by their basic healthcare package's 'restrictiveness' level based on factors described in Chapter 2 (Figure 2).[51] The Belgian package ranked the most restrictive and the Dutch package the most non-restrictive. Rather than simply being the sum of the scores for the factors in Figure 2, our ranking process implicitly weighted these factors' relative importance since they interrelate and vary in significance.

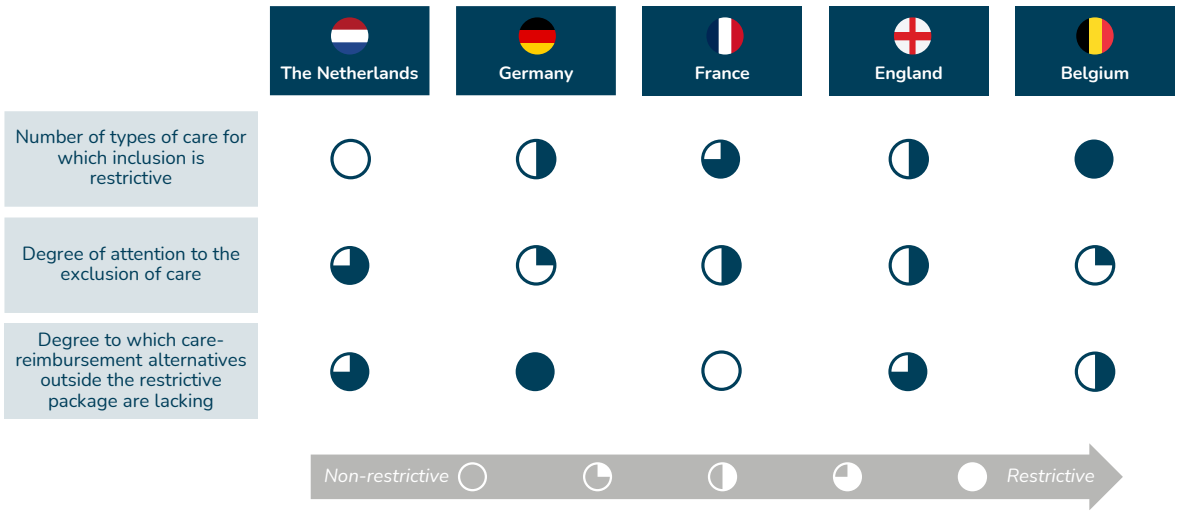

Figure 2. We ranked the Belgian package as the most 'restrictive' and the Netherlands' package as the most 'non-restrictive' based on weighted scores for each variable.

[51] This ranking focuses exclusively on curative care, excluding (expensive) medications and physiotherapy.

3.1 There is no clear link between a country's reimbursement for 34 treatments and devices and the restrictiveness of its basic healthcare package

We analysed reimbursement practices in the Netherlands, Germany, France, England and Belgium for 34 treatments and medical devices (see Appendix 3). We selected these treatments and medical devices based on the Health Care Institute's reviews, supplemented by HTA effectiveness assessments in the comparison countries (see Appendix 1 for an overview of the selection process). Of the 34 treatments and medical devices examined, 27 are part of the basic health insurance package in the Netherlands (see §3.1.1). The remaining seven treatments and medical devices are not within the Dutch basic package (§3.1.2).

3.1.1 Reimbursed treatments and medical devices in the Netherlands are often reimbursed in countries with more restrictive basic healthcare packages

Germany, France and England reimburse almost all the treatments and medical devices examined

Germany, France and England reimburse most (around 80%) of the 27 treatments and medical devices examined (Figure 3). Reimbursement does not seem to correlate with the type of package, as outlined below:

- For nine treatments and medical devices, reimbursement practices in Germany, France and England are the same as in the Netherlands.
- Germany reimburses for one medical device (the Left Ventricular Assist Device [LVAD]) more broadly than in the Netherlands, where it is only included in the basic health package when used as destination therapy following multidisciplinary diagnosis by trained professionals. Compared to the Netherlands, Germany's criteria for using the LVAD are less strict, while France's and England's are similar.
- Dutch reimbursement practice is less restrictive from that in one other country (Germany, France or England) for 15 treatments and medical devices.
- For two treatments,[52] Germany and France either do not reimburse or reimburse less widely than the Netherlands.

[52] Repetitive Transcranial Magnetic Stimulation (rTMS) in treating depression and measurement of the amount of nitric oxide asthma in exhaled air in treating asthma (fractional exhaled nitric oxide).

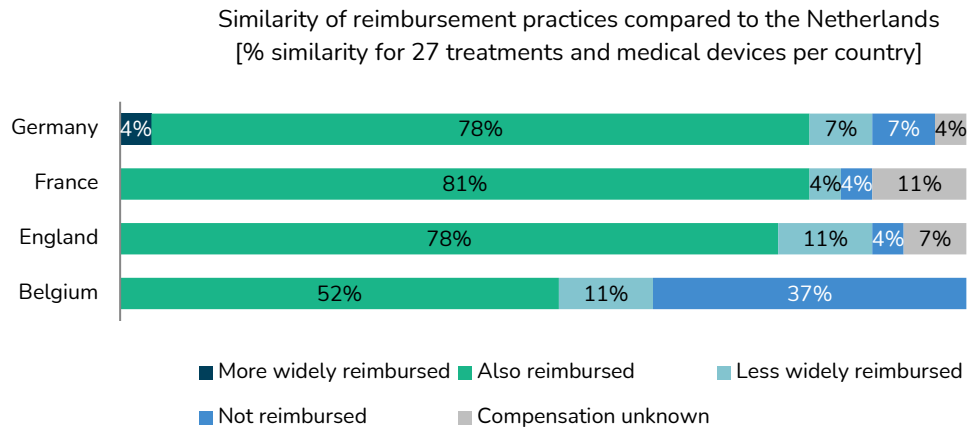

Figure 3. Most (around 80%) of the 27 treatments and medical devices in the Netherlands' basic health insurance package are also reimbursed in Germany, England, and France. In Belgium, about half of treatments the Dutch Health Care Institute considers effective are not covered. The remaining 7 out of 34 treatments and medical devices are not included in the Dutch basic health insurance package and are therefore not represented in this figure. Source: SiRM analysis.

Belgium does not reimburse some of the treatments and medical devices the Dutch Health Care Institute deems effective

Belgium reimburses 52% of the treatments and medical devices examined in a similar way to the Netherlands. Of the remaining 48%, it reimburses some less generously and some not at all (Figure 3), applicable to inpatient and/or outpatient care and diagnostic and therapeutic treatments and medical devices.

Why Belgium reimburses these treatments and medical devices less generously or not at all is largely unknown. In one case, a reimbursement discrepancy was due to a different understanding of the treatment's effectiveness.[53] The Dutch Health Care Institute considers the other care types not reimbursed in Belgium effective, and they are applied and prescribed by doctors. As several interviewees also mentioned, this difference indicates that innovations enter the basic healthcare package less easily in Belgium than in countries with a non-restrictive system.

3.1.2 Countries with a more restrictive system regularly reimburse treatments not reimbursed in the Netherlands

At least one of the comparison countries reimburses the seven treatments[54] not included in the Netherlands' basic healthcare package. Examining reimbursement status per country yields 28 treatment-country combinations ('items'), all involving inpatient treatments. Of these, 57% are reimbursed in the comparison countries (see Figure 4).[55]

[53] This concerned the difference between the KCE's position on thermal ablation and that of the Care Institute/Integraal Cancer Centre Netherlands (IKNL). Also, potential time differences in the effectiveness assessments in Belgium and the Netherlands may come into play as well. In Belgium, the effectiveness assessments dates back to 2012, whereas in the Netherlands, the positional review of the National Health Care Institute was published in 2017.
[54] Of the treatments and medical devices included in this analysis (see Appendix 1), none of the medical devices were *not* reimbursed in the Netherlands.
[55] We do not break this down by country in percentage terms due to the low case numbers.

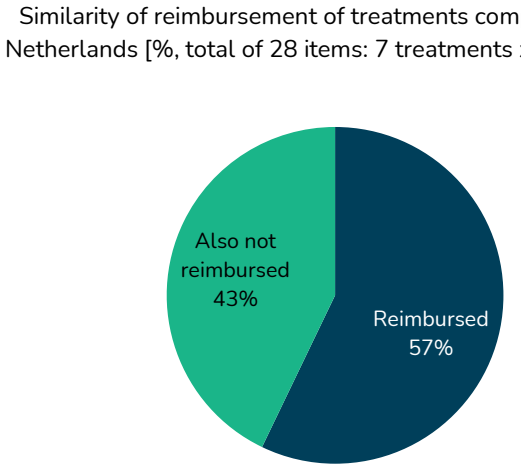

Figure 4. Germany, England, France and/or Belgium reimburse over half of the 28 items (7 treatments x 4 countries) not reimbursed in the Netherlands. Source: SiRM analysis.

Germany and France appear to reimburse for the most part. In England, as in the Netherlands, most treatments are not reimbursed. In contrast to the Netherlands, three of the seven examined treatments are reimbursed in Belgium, although the reasons are unknown. In these cases, at least one of the comparison countries also reimburses the treatment, while the Dutch Health Care Institute assesses that these treatments' effectiveness is not scientifically proven.

3.2 In practice, comparison countries reimburse more care than expected based on their regulation of the basic healthcare package

There is a difference between how basic healthcare regulation works in theory and the healthcare a country ultimately reimburses.

First, cultural aspects play a role in reimbursement discussions. In Germany, the IQWiG rejected the scientific argument for reimbursing the NIPT test for all pregnant women, reimbursing it only for pregnant women with high-risk pregnancies.[56] Despite this, the NIPT is reimbursed for all women without reference to their risk, partly because of the cultural preference (given Germany's history) not to exclude groups. Similarly, reimbursement often has no conditions attached, such as requiring patients to lose weight before knee replacement surgery.

Second, politics also plays a role in care reimbursement, predominantly aiming to increase the basic healthcare package. In Germany, for example, the Minister for Health decided to reimburse liposuction for lipedema stage III, despite the G-BA's unfavourable decision.[57] In Belgium, the federal parliament approved a proposal to expand the available healthcare budget by €200 million to reimburse primary care psychologists.[58]

[56] IQWiG Abschlussbericht S16-06 (2018). Nicht invasive Prënataldiagnostik (NIPD) zur Bestimmung des Risikos autosomaler Trisomien 13, 18 und 21 bei Risikoschwangerschaften.
[57] As indicated by an interviewee from Germany.
[58] See (among others): https://vvkp.be/nieuws/200-miljoen-eu-voor-elp-op-jaarbasis

Thirdly, it is impossible at a national level to define and control the care healthcare professionals provide in practice. For example, Belgium defines its fee schedule nationally through service descriptions and associated tariffs, yet interviewees indicate that healthcare professionals sometimes stretch these service descriptions in practice. However, we cannot verify this for sickness funds.

3.3 Despite the Netherlands' non-restrictive inclusion of new care in its basic healthcare package, it has the lowest curative-care expenditure of all the comparison countries

As a percentage of gross domestic product (GDP), curative-care spending is lower in the Netherlands than in any of the comparison countries (Figure 5).[59-60] We see no correlation between a country's macro-level spending and its basic healthcare package's restrictiveness.

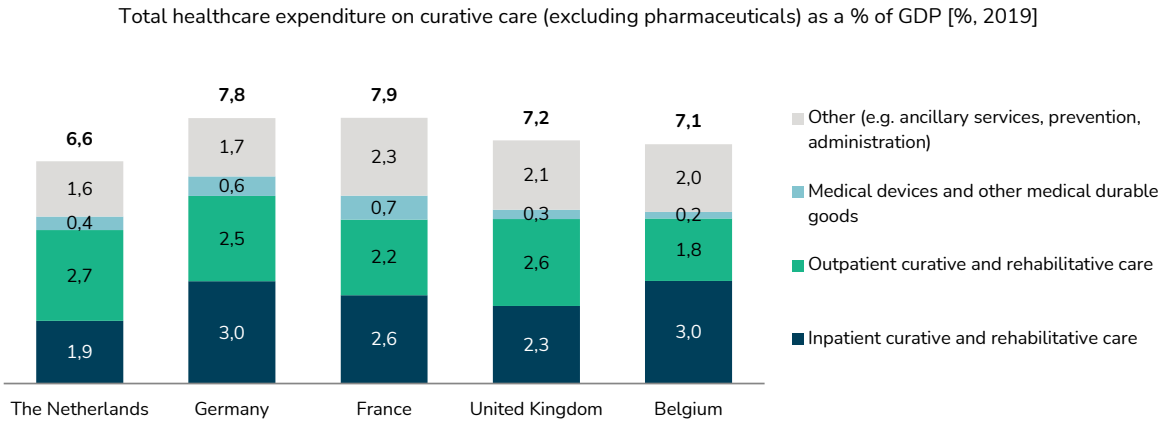

Figure 5. As a percentage of gross domestic product (GDP), curative-care spending is lower in the Netherlands than in any of the comparison countries. There is no evidence of a relationship between macro-level spending and the restrictiveness of a country's basic healthcare package. Data for 2019 related to Covid-19. Source: Eurostat (2023). Healthcare expenditure by function.

The Netherlands' comparatively low curative-care expenditure may reflect the macro budget available for (curative) care. Regardless of how restrictive or non-restrictive the basic healthcare package is, healthcare professionals must decide whether they consider it clinically and cost-effective to use specific treatments or medical devices, even if they are (in principle) reimbursed. In the Netherlands, agreements have been made with various healthcare sectors in outline agreements (HLAs) on maximum budget growth space at the macro level since 2012. Belgium also reviews the scope for macro-level growth in healthcare spending annually. In France, the government regulates about 75% of healthcare spending across healthcare sectors.

[59] More recent data was unavailable (for all countries and/or complete). We used UK data because data for England was unavailable.

4. Reflection: The Netherlands appears to be a frontrunner despite its non-restrictive package

It became evident throughout this research that the Netherlands appears to be at the forefront of current approaches to regulating healthcare packages, despite its relatively 'non-restrictive' package compared to the other countries. The Ministry of Health, Welfare and Sport and the Dutch Health Care Institute are collaborating on a more future-proof approach to package regulation (§4.1). Dutch healthcare is working to provide exclusively *effective* care in practice (§4.2). However, the national price negotiations in France, particularly for extramural medical devices, present an interesting reference point (§4.3). Whether such approaches are applicable in the Dutch context warrants further investigation.

In this chapter, we, as researchers, reflect upon the regulation of the basic healthcare package in the Netherlands, describing key findings not directly addressed in the responses to the research questions.

4.1 The Ministry and the Health Care Institute are collaborating on a more future-proof package regulation

Interviewees in Belgium and Germany indicated they are looking to the Netherlands to draw lessons for their package regulation, particularly the Ministry of VWS and the Health Care Institute's recent shift towards a more future-proof regulation of the basic statutory healthcare package. These developments focus on improving control over the package's scope and practical application by proactively and impactfully identifying and addressing package-related issues, enhancing and broadening the basic package's assessment for curative and long-term care and addressing appropriate care use and exclusion.

Proactively and impactfully identifying and addressing package-related issues

In its recent publication, 'Package Management in Practice 4: Package Management as a Solid Foundation for Appropriate Care,' the Health Care Institute commits to proactively and impactfully identifying and addressing package-related issues. It aims to achieve this by detecting package-related risks earlier and more systematically, including through horizon scanning to monitor upcoming healthcare services. Additionally, the Health Care Institute aims to introduce 'cyclical' regulation of the basic healthcare package, which involves reevaluating care as needed.

In collaboration with field stakeholders, the Health Care Institute developed the Package Agenda 2023–2025[61] in July 2023, which includes joint selection criteria for addressing package-related issues. These include disease burden, workforce impact, practice variation, financial impact, climate and environmental impact, and the degree of health benefit for patients. The package agenda also features 13 priority topics for 2023–2025.

SiRM believes prioritising package-related issues based on comprehensive selection criteria, including financial impact, is beneficial. We view the package agenda's collaborative development with healthcare parties positively, enabling a collective direction for the future of the regulation of the basic healthcare package in the Netherlands. Scheduling and prioritising package-related issues was not always systematic and transparent in the countries we studied. Moreover, the Health Care Institute issued numerous positions on treatments and medical devices between 2013 and 2023 with relatively minor cost impacts (see §2.3.1, Figure 1).

Enhancing and broadening the basic package's assessment for curative and long-term care

In addition to systematically addressing package-related issues, the Ministry of VWS and the Health Care Institute aim to enhance and broaden the basic package's assessment for curative and long-term care[62]:

- The current effectiveness assessment should focus more explicitly on outcome measures such as patient quality of life and treatment side effects. Furthermore, the Health Care Institute provides more insight in the 2023 Update Assessment of State of Science and Practice[63] about how the assessment framework offers flexibility in dealing with uncertainties about treatment and/or medical device effectiveness.
- Other package criteria should carry more weight, potentially supported by legal and regulatory foundations. Examples include cost-effectiveness, required workforce capacity, necessity and feasibility. Additional conditions should also be established for admission to the basic package to promote appropriate usage, and attention should be given to sustainability and environmental impact.
- Although assessments are rarely conducted for long-term care due to the differences with curative care, the Ministry of VWS and the Health Care Institute aim to work on regulation of the basic healthcare package for long-term care to address concerns about whether the current long-term care quality is sufficient and affordable in the future.

While SiRM acknowledges the significance of improving and broadening the basic package's assessment to maintain healthcare accessibility, we also caution against viewing regulation of the basic healthcare package as a 'silver bullet':

- The information needed to assess package criteria may not always be available, particularly in sectors such as long-term care. Assembling sufficient information will require substantial

[61] Zorginstituut Nederland (2023). Pakketagenda passende zorg 2023 – 2025. See: https://www.zorginstituutnederland.nl/publicaties/publicatie/2023/07/18/pakketagenda-passende-zorg
[62] Minister van Volksgezondheid, Welzijn en Sport, Kamerbrief 'Hoofdlijnen verbeteren en verbreden toets op het basispakket', 2 december 2022.
[63] Zorginstituut Nederland (2023). Beoordeling stand van de wetenschap en praktijk 2023. Zie: https://www.zorginstituutnederland.nl/publicaties/publicatie/2023/04/11/beoordeling-swp-2023#:~:text=In%20de%20actualisatie%20van%20het,zij%20het%20beoordelingskader%20kunnen%20toepassen.

time and attention, raising questions about whether this effort outweighs the expected time investment for healthcare professionals.

- The Health Care Institute faces the challenge of balancing the expanded package criteria, potentially leading to societal debates. Therefore, it is advisable to explicitly define the package criteria before making decisions. Transparency and public involvement in decision-making are crucial.
- Package decisions will increasingly depend on determining the appropriate patient groups for whom a treatment or medical device is suitable. However, these decisions are not black and white, and healthcare providers' and purchasers' information base needs strengthening to navigate these grey areas. For instance, health insurers in the Netherlands have minimal knowledge of which care is provided for which patients, partly due to the Diagnostic-Related Group (DRG) system. Greater insight would help them fulfil their roles more effectively.

Addressing appropriate care usage and exclusion

The Health Care Institute plans to strengthen appropriate usage by providing recommendations, establishing agreements, and introducing additional conditions for insured care if necessary. Additionally, it aims to enhance the exclusion of care no longer meeting legal criteria by listing topics deemed suitable for this purpose on the ZE&GG program's implementation agenda. This step can occur following a position on care by the Dutch Health Care Institute.

4.2 The healthcare sector aims to provide exclusively *effective* care in practice

In the ZE&GG program, stakeholders from the medical-specialist care sector in the Netherlands collaborate to phase out ineffective care from the package. The program aims to implement effective care, de-implement ineffective care when evidence is available, and evaluate existing care when there is insufficient information regarding its appropriateness for patients.

The ZE&GG program aims to integrate healthcare evaluation into the regular healthcare system to promote appropriate usage, using the so-called Circle of Appropriate Use to assess interventions' value and implement the results in practice.

The ZE&GG program's current assignment and funding conclude in July 2024. However, the healthcare sector has agreed to continue and expand its approach. The Ministry of VWS is developing a follow-up assignment, ensuring some continuation of the current program. Additionally, the Ministry of VWS is working on assignments to expand the Circle of Appropriate Use from medical specialist care to other curative care sectors.

Despite the program's successes, there has not yet been a formal evaluation of whether it has achieved its objectives. A similar evaluation of the EBI[64] program in England demonstrated that it is impossible to adequately demonstrate its impact after only a few years, which we expect might also be true in the Netherlands. Quantifying the impact is also likely challenging, as it involves a cultural shift with various interests at play. In practice, phasing out ineffective care is challenging

[64] Evidence-Based Interventions.

and likely to take considerable time. Guidelines must be adjusted, and some service funding might need to be stopped or modified. Moreover, since the healthcare profession has become accustomed to certain practices, there may be a desire to retain obsolete care.[65]

4.3 National price negotiations in France present an interesting reference point

Based on France's experiences, we believe there are still opportunities in the Netherlands to link for medical devices the regulation of the basic healthcare package to the prices paid for them. In France, the Comité Economique des Produits de Santé (CEPS)[66] negotiates prices for extramural medical devices at the national level, primarily based on the devices' relative effectiveness (determined and advised by CNEDIMTS as part of HAS). Prices can be renegotiated following HAS reevaluation. Interviewees in France were enthusiastic about the national price negotiations because they have generated significant savings on collective expenditures for medical devices.

We expect France's example may offer lessons for the Netherlands, particularly for medical devices with a substantial budgetary impact and for which manufacturers hold a monopoly position. However, this approach's suitability for the Dutch context needs further investigation, especially since earlier research indicated limited support for a 'gatekeeping' mechanism for medical devices similar to that for high-budget impact pharmaceuticals.[67]

[65] Zorginstituut (2023): 'Pakketbeheer in de Praktijk 4: Pakketbeheer als solide basis voor passende zorg'.
[66] CEPS is an interministerial committee comprising representatives from the ministries responsible for health, economy and research and representatives from health insurers and supplementary health insurance.
[67] Berenschot (2021): 'Een sluis voor toelating van MedTech middelen: een goed idee?'.

Appendix 1. Research approach

We conducted approximately 25 interviews with experts from the Netherlands and comparison countries for this study (Table 1) and conducted extensive desk research.

Table 1. We interviewed 25 stakeholders in regulating statutory healthcare coverage in the countries examined.

Country	Organisation	Name
Netherlands	Federation of Medical Specialists (Federatie Medisch Specialisten)	Teus van Barneveld Raphael Hemler
	Care Evaluation & Appropriate Use programme (Zorgevaluatie & Gepast Gebruik – ZE&GG)	Sjoerd Repping
	Netherlands Health Care Institute (Zorginstituut Nederland)	Rashmi Jadoenandansing Angeli van der Zwaag Jacqueline Zwaap
	Health Insurers Netherlands (Zorgverzekeraars Nederland)	Christine Ritoe
Belgium	Christian Mutualities - health insurance fund (Christelijke Mutualiteit)	Hervé Avalosse Bernard Landtmeters Koenraad Pauwelyn Viviane Van Elshocht
	National Institute for Sickness and Disability Insurance (Rijksinstituut voor Ziekte en Invaliditeitsverzekering – RIZIV)	Marleen Louagie
	Solidaris - health insurance fund	Bart Demyttenaere
Germany	Federal Joint Committee (Gemeinsamer Bundesausschuss – G-BA)	Matthias Perleth
	The National Association of Statutory Health Insurance Funds (Spitzenverband Bund der Krankenkassen)	Friederike Kuhnt Eckart Schnabel
	Health Systems in Transition (co-author) / Technische Universität Berlin	Anne Spranger
England	Academic Health Science Network / National Institute for Health and Care Excellence (NICE)	Nicola Bent
	Evidence-Based Interventions Programme / Royal Free London NHS Foundation Trust / NHS England / National Institute for Health and Care Excellence (NICE)	Aoife Molloy
	NHS West Yorkshire Integrated Care Board / York Hospitals NHS Foundation Trust / NHS England	Catherine Thompson

Country	Organisation	Name
France	High Authority of Health (Haute Autorité de Santé – HAS)	Valérie Paris
	Health Systems in Transition (co-author) / Assistance Publique Hôpitaux de Paris	Isabelle Durand-Zaleski
	National Health Insurance Fund (Caisse Nationale de l'Assurance Maladie – CNAM) / HAS	Dominique Polton
Sweden	Swedish Agency for Health Technology Assessment and Assessment of Social Services (SBU)	Sophie Söderholm Werkö
	Swedish Association of Local Authorities and Regions (Sveriges Kommuner och Regioner - SKR)	Sofia Medin

We investigated which types of restrictive basic healthcare packages operate internationally based on interviews and desk research. We also conducted two comparative analyses of the relationship between a country's basic healthcare package's restrictiveness and care reimbursement.

We initially tried to use Health Technology Assessment (HTA) organisations' effectiveness assessments in each country to identify differences in care reimbursement. However, this analysis did not provide sufficient insight since there were only eight cases where two or more countries conducted an effectiveness assessment for a comparable care type and patient group – too small a sample to draw general conclusions. In addition, effectiveness assessments did not always appear to guide reimbursement in practice. As a result, most of this analysis does not appear in the main report. However, the analysis yielded interesting results, as outlined in Appendix 2.

Based on our experiences during the first analysis, we subsequently investigated the relationship between a basic healthcare package's restrictiveness and reimbursement practices for 34 case studies identified in the Health Care Institute's issued reviews from the past ten years. We selected 26 relevant reviews from these, supplemented with the eight cases where effectiveness assessments were also issued in at least two countries studied. For all 34 cases, we analysed current reimbursement practices in Germany, France, England and Belgium. Based on this analysis, we drew the conclusions described in Chapter 3. Below, we explain our case selection in more detail and discuss the sources and search strategy used to map reimbursement practices.

Case-study analysis and reimbursement practices

We selected 34 cases for examining reimbursement practices (Figure 6) via the following process:

- We first identified all Health Care Institute positions from the past ten years (2013-2023, n=118).
- We excluded reviews not involving a position on the State of Science and Practice[68] (n=30) or for which a revised version has since been released (n=6). We excluded four more that

[68] This included, for example, ZVW disputes/views on whether specific services should be covered by the Health Insurance Act (e.g. second opinion and interpreter provision in healthcare).

were less relevant due to other reasons, e.g. positions with conditional authorisation or without a clear statement from the Health Care Institute.[69]

- We then excluded cases for which no cost impact was available in the Health Care Institute's position paper. For cases with a known but relatively low-cost impact (below €5 million), we only included them if the budget impact[70] was known and positive.
- A total of 26 cases remained, including 19 with a cost impact higher than €5 million.
- To avoid only including cases discussed in the Netherlands, we supplemented the selected positions with eight cases based on the analyses of international HTA organisations' effectiveness assessments (see Appendix 2).

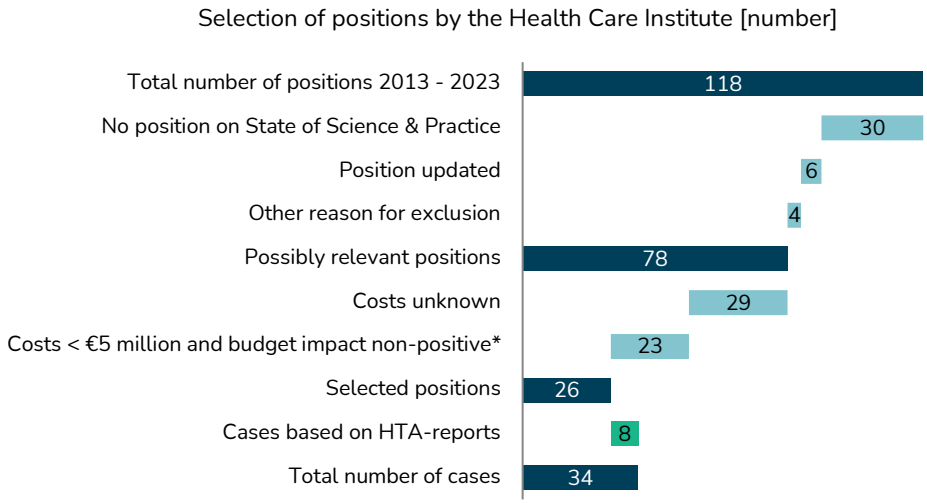

Figure 6. We selected a total of 34 cases to analyse international reimbursement practices based on several criteria.

Sources and search strategy for analysing reimbursement practices

To determine reimbursement practices in the comparison countries, we distinguished 'definitive' and 'complementary' sources, accounting for the country's context. We drew conclusions about reimbursement practices based on the strength of evidence for each source (see Table 2).

[69] For instance, in the position paper on professional therapy and daycare in the mental healthcare sector, the Care Institute concluded that there is insufficient evidence of effectiveness. However, professional therapy has been common practice for years. The Care Institute, therefore, decided that further research is needed and vocational therapy and daycare in the mental healthcare sector should remain within the insured package in the meantime.
[70] The budget impact refers to the additional cost compared to the cost of standard treatment.

Table 2. We characterised reimbursement practices by country based on different evidential sources.

Type of source	Conclusion
'Definitive' sources or multiple additional sources of sufficient quality	(Not) reimbursed
'Supplementary' sources only	Appears to be (not) reimbursed
No information and non-restrictive entry into the basic healthcare package	Appears to be reimbursed
No information found by the SiRM team or the Health Care Institute when drafting their position and restrictive entry into the basic healthcare package	Does not appear to be reimbursed
No information found by the SiRM team and restrictive entry into the basic healthcare package	Unknown[71]

'Definitive' sources

- We started each case study using the Health Care Institute's documentation's details on reimbursement practices, views and/or inclusion in guidelines by country.
- We then searched for at least the following in each country:
  - Belgium: nomenclature(s), documents and/or information on RIZIV websites, statements interviewee(s).
  - Germany: G-BA decisions and/or guidelines, statements interviewee(s).
  - England: various forms of NICE guidance[72] (initially searching for Technology Appraisals).
  - France: reviews/evaluations/guidelines on the HAS website, inclusion in LPPR list[73] and liste positive intra-GHS.[74]

'Additional' sources

- If we did not find a 'definitive' source, we searched for additional information via Google, yielding several sources:
  - Patient association websites.
  - Hospital websites.
  - Scientific articles focused on market access.
  - The European Network for HTA (EUnetHTA).

[71] This was particularly true for Belgium, despite having a system under which a reimbursed treatment and/or medical device would be expected to feature in the national fee schedule. However, care is reimbursed in other ways in practice, e.g. by giving a different code number or via the Special Solidarity Fund. Thus, we ultimately found a source for all cases in Belgium.
[72] In addition to technology appraisals, NICE develops guidance for diagnostics, interventional procedures and medical technologies, among others.
[73] Liste des Produits et des Prestations Remboursable (including the liste en sus containing invasive medical devices and implants)
[74] List of high-risk medical devices reimbursed within DBCs.

- Where we found no definitive or additional source, we added specific questions about particular treatments' reimbursement to the interview protocol in Belgium, France and Germany.

Appendix 2. Analysis of published effectiveness assessments

Approach

We analysed effectiveness assessments of curative care published by Health Technology Assessment (HTA) organisations in the Netherlands, Belgium, France and Sweden over the past 20 years, classifying them by category, type and year. Although automated downloads of all HTA reports' titles and subjects proved difficult for Germany[75] and England,[76] general data on the number and type of effectiveness assessments were known for both countries. When effectiveness evaluations seemed similar in at least two countries, we manually checked whether Germany or England had also conducted an effectiveness evaluation on the same topic.

This approach yielded 38 effectiveness evaluations on the same treatment or medical device in two or more countries. We excluded 30 of these after closer examination, e.g. because the specific patient groups[77] or exact treatment[78] appeared to differ. Eight cases remained where at least two countries assessed a particular treatment's or medical device's effectiveness for a similar patient group.

We only analysed effectiveness assessments published by national HTA organisations. Effectiveness assessments conducted by Belgium and Germany's HTA organisations (the KCE and IQWiG, respectively) do not formally link to the decision-making bodies (RIZIV and G-BA). The RIZIV and G-BA also have independent committees that conduct effectiveness assessments.[79] Since these are not publicly published, we did not include them in this analysis.

Results

The number of effectiveness assessments conducted over the past 20 years varies significantly by country

How many effectiveness assessments HTA organisations published over the past 20 years varies significantly across countries (Figure 7). Among the countries studied, England and France have conducted the highest number of effectiveness assessments. However, specific data on the number of effectiveness assessments are not available (indicated by the striped bars in Figure 7). NICE carries out numerous effectiveness assessments for developing guidelines and other forms

[75] The IQWiG website did not appear to allow data-scraping by review type.
[76] Because NICE conducts effectiveness assessments for all new treatments, data-scraping would involve too much manual work.
[77] For example, the effectiveness assessments for next-generation sequencing involved diagnostics in children in England and diagnostics in women with early-stage breast cancer in the Netherlands.
[78] For example, the effectiveness assessments for endovascular treatment of complex aneurysms in the aorta appeared to concern a different part of the aorta (abdominal) in Belgium than in the Netherlands (the descending aorta).
[79] For example, RIZIV includes a committee that conducts effectiveness assessments for medical devices and implants (the Commission for Invasive Medical Devices and Implants [CTIIMH], while G-BA has a committee that conducts effectiveness assessments for paramedical care.

of NICE 'guidance', but publishes relatively few 'Technology Appraisals' (which are are formally tied to reimbursement in practice). Similarly, there is no available data on the precise number of effectiveness assessments conducted by HAS in France. An interviewee indicates that HAS evaluates approximately 130-160 medical devices from specific manufacturers per year. The Health Care Institute ranked third in terms of the number of effectiveness assessments conducted over the past 20 years.

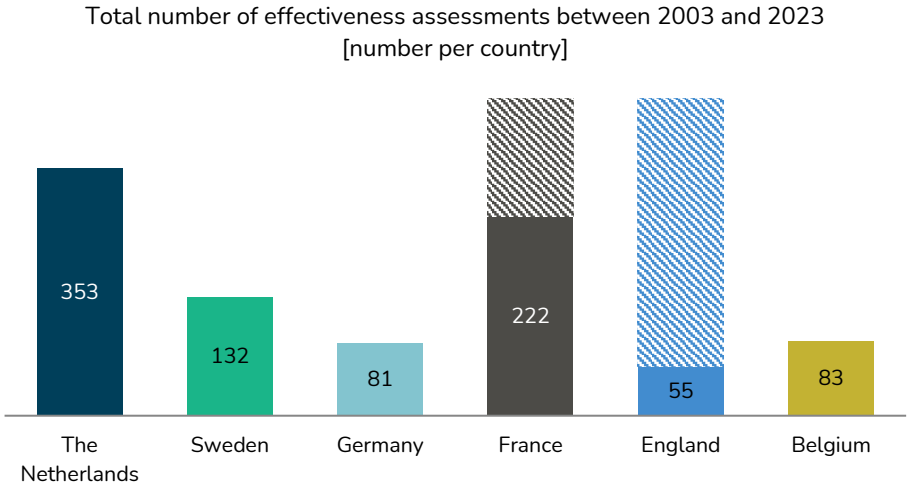

Figure 7. The number of effectiveness assessments HTA organisations conducted in the past 20 years varies widely by country. Note: For England, this graph and other graphs in this appendix only include NICE's Technology Appraisals, for which procurement and funding are formally linked to a favourable recommendation. NICE conducts further effectiveness appraisals for other guidelines (see the dashed bar). Specific numbers are unknown, but the quantity is likely higher than the number of reviews in the Netherlands. For France the effectiveness assessment for medical devices for specific manufacturers are not included, since exact numbers are unknown. Source: data analysis SiRM based on data from websites Zorginstituut Nederland, SBU, IQWiG, HAS, NICE and KCE.

Based upon available data, HAS published the most effectiveness of all studied countries between 2018 and 2023, while the number of assessments by the Health Care Institute decreased (Figure 8). We were unable to include the 'striped bars' from Figure 7 in this analysis. In practice, the number of effectiveness assessment in France and England is therefore higher.

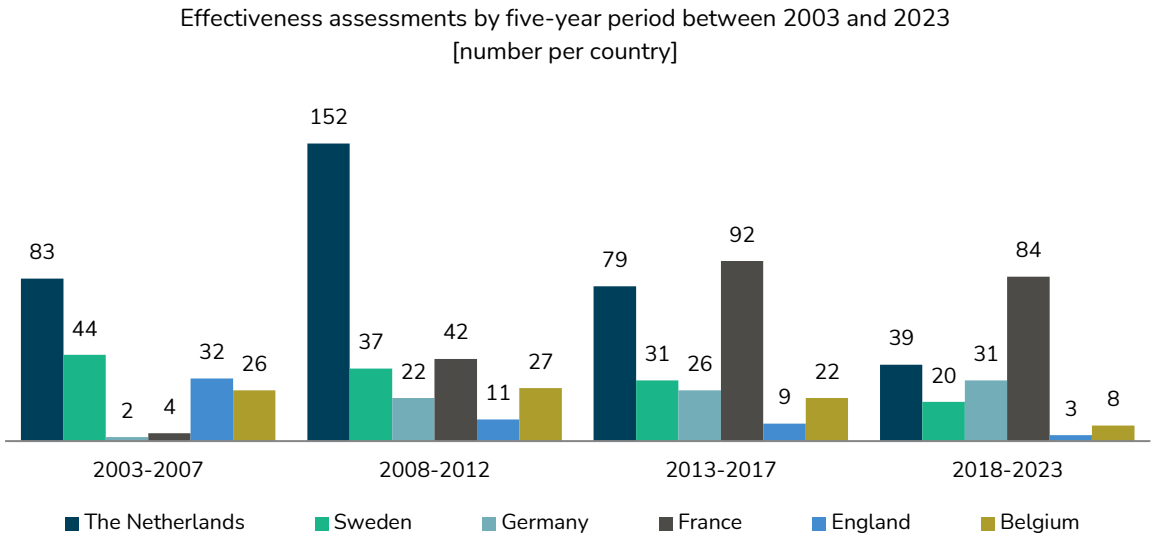

Figure 8. Based upon available data (excluding the striped bars in Figure 7), the Dutch Health Care Institute published the most reviews in total – compared to the other countries - between 2003 and 2017 (the first three time periods shown in the graph). In France, HAS published the most effectiveness assessments between 2018 and 2023 compared to the other countries. Source: data analysis SiRM based on data from websites Zorginstituut Nederland, SBU, IQWiG, HAS, NICE and KCE.

The care types for which effectiveness assessments are conducted vary by country

Effectiveness assessments are conducted for various care types in the comparison countries (Figure 9). In the Netherlands, the Health Care Institute mainly assesses treatments (including, for example, bariatric surgery and medical devices such as negative pressure wound therapy). In contrast, France focuses also on medical tests (such as next-generation sequencing in breast cancer), next to procedures and medical devices. In England there are no published Technology Appraisals for medical tests – although NICE publishes recommendations in its 'Diagnostics Guidance' that may cover medical tests. Germany focuses primarily on preventive interventions, such as cancer screening and prenatal testing.

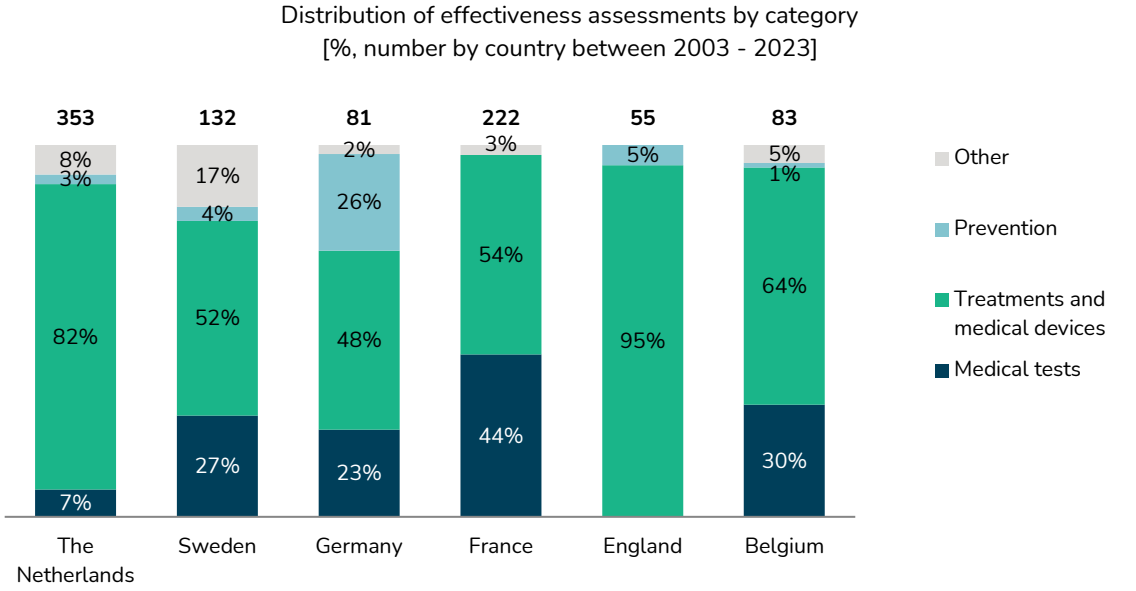

Figure 9. The care types for which effectiveness assessments are conducted vary by country. Source: data analysis SiRM based on data from websites Zorginstituut Nederland, SBU, IQWiG, HAS, NICE and KCE.

The treatment types for which effectiveness assessments are conducted also vary by country

The type of treatments and medical devices for which effectiveness assessments are conducted also vary by country (Figure 10), although no information was available for Germany and England. The Health Care Institute primarily assesses surgical treatments, with the 'other' category comprising very different treatment types, such as post-treatment for Lyme syndrome and inpatient admission for children with severe obesity. This diversity may be due to the Health Care Institute's agenda-setting for effectiveness assessments via stakeholders (especially health insurers and healthcare providers). Sweden also has a relatively large proportion of effectiveness assessments for 'other' treatment types, with similarly non-restrictive entry into the basic healthcare package and HTA agenda-setting that goes through stakeholders. In France, almost half of the effectiveness assessments concern implants and prosthetics. In Belgium, implants,

prosthetics, robotics and other such devices account for a quarter of treatment effectiveness assessments.

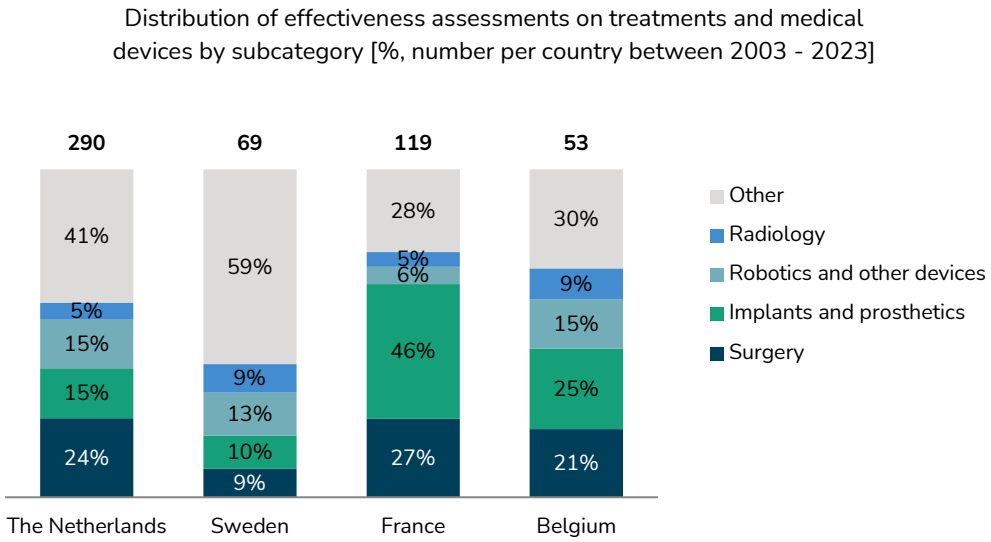

Figure 10. The type of treatments and medical devices for which effectiveness assessments have been published varies significantly by country. Data were not available for Germany and England. Source: SiRM data analysis using data from the following websites: Zorginstituut Nederland, SBU, HAS and KCE.

Few of the effectiveness assessments in comparison countries reviewed the same treatment, and if they did, the timing varied considerably

When different countries conducted effectiveness assessments for the same treatment, the timing of the assessment varied significantly. Out of 874 effectiveness assessments, there were only eight cases where HTA organisations assessed the same treatment for the same patient group, but these were conducted at different time points (Table 3). Thus, despite Belgium and England having similarly restrictive basic healthcare packages, the KCE in Belgium issued an effectiveness assessment on the Implantable Cardiac Defibrillator (ICD) as early as 2008, while NICE did not issue a Technology Appraisal until 2014 in England. Conversely, NICE released an effectiveness appraisal on the Left Ventricular Assist Device (LVAD) ten years earlier than KCE and even fifteen years before the HAS.

Table 3. Different countries assessed the same treatment at different time points. We only analysed the most recent effectiveness assessment.

	Netherlands	Sweden	Germany	France	England	Belgium
Implantable cardiac defibrillator (ICD)		2006		2022	2014	2008
Left ventricular assist device (LVAD)	2015			2021	2006	2016
Repetitive Transcranial Magnetic Stimulation (rTMS)	2011			2022	2015	
Negative pressure wound therapy (NPWT)		2011	2006		2019	2008

	Netherlands	Sweden	Germany	France	England	Belgium
Hyperbaric Oxygen Therapy (HBOT)	2009		2016	2014		2008
Proton therapy (children)	2011	2021				2015
Proton therapy (adults)	2010	2021				2019
Continuous glucose monitoring (CGM)	2010	2013	2015	2022		

The low number of effectiveness assessments on the same treatment and their discrepant timing is striking. We would expect a new treatment's application to enter the basic healthcare package and subsequent effectiveness assessment to occur at a similar time in neighbouring countries (e.g. when a particular medical device becomes available on the market). This discrepancy aligns with our finding that the role of effectiveness assessments and agenda-setting priorities differ across countries (see Chapter 2).

Appendix 3. Reimbursement of 34 care types in the countries examined

We analysed reimbursement practices for 34 treatments and medical devices in Belgium, Germany, England and France (Table 4. See Appendix 1 for a description of how we selected these treatments and medical devices). In this, we drew conclusions based on the strength of the evidence (see Appendix 1). Of the 34 treatments examined, 27 treatments and medical devices are reimbursed for the same indications as in the Netherlands (see §3.1.1), and seven are not (see §3.1.2).

Table 4. Reimbursement practices in Germany, France, England and Belgium for 34 treatments/medical devices.

Treatment name[80]	Inpatient/ outpatient	Type of treatment	Reimbursement practice				
			Netherlands	Germany	France	England	Belgium
Flash Glucose Monitoring (FGM)	Outpatient	Medical device	Reimbursed	Reimbursed	Reimbursed	Reimbursed	Reimbursed
Interdisciplinary specialist medical rehabilitation (IMSR)	Inpatient	Therapeutic procedure	Reimbursed	Reimbursed	Appears to be reimbursed	Reimbursed	Reimbursed
Transcatheter aortic valve implantation (TAVI)	Inpatient	Medical device	Reimbursed	Reimbursed	Reimbursed	Reimbursed	Reimbursed
Autologous fat transfer (AFT) in breast cancer	Inpatient	Therapeutic procedure	Reimbursed	Not reimbursed	Reimbursed	Reimbursed	Reimbursed
Ductoscopy for pathological nipple discharge	Inpatient	Diagnostic procedure	Reimbursed	Reimbursed	Appears to be reimbursed	Not reimbursed	Not reimbursed

[80] If the treatment was assessed in the Netherlands, the treatment name aligns with the Care Institute's position. For treatments not assessed in the Netherlands, we have used the IQWiQ, HAS, NICE or KCE report names.

Treatment name[80]	Inpatient/ outpatient	Type of treatment	Reimbursement practice				
			Netherlands	Germany	France	England	Belgium
Left ventricular assist device (LVAD)	Inpatient	Medical device	Reimbursed	Widely reimbursed	Reimbursed	Reimbursed	Reimbursed
Adjuvant Hyperthermic Intraperitoneal Chemotherapy (HIPEC) for ovarian carcinoma	Inpatient	Therapeutic procedure	Reimbursed	Reimbursed	Reimbursed	Reimbursed	Less widely reimbursed
Holmium-166 radioembolisation (QuiremSpheres)	Inpatient	Therapeutic procedure	Reimbursed	Reimbursed	Appears to be reimbursed	Less widely reimbursed	Reimbursed
Autologous fat transplantation (AFT) for partial defects of the breast	Inpatient	Therapeutic procedure	Reimbursed	Unknown	Reimbursed	Reimbursed	Reimbursed
Descemet membrane endothelial keratoplasty (DMEK)	Inpatient	Therapeutic procedure	Reimbursed	Reimbursed	Appears to be reimbursed	Reimbursed	Reimbursed
Thermal ablation	Inpatient	Therapeutic procedure	Reimbursed	Reimbursed	Appears to be reimbursed	Reimbursed	Not reimbursed
Tiered tinnitus-specific treatment	Outpatient	Therapeutic procedure	Reimbursed	Appears to be reimbursed	Unknown	Reimbursed	Not reimbursed
Tumour-infiltrating lymphocytes (TIL)	Inpatient	Therapeutic procedure	Reimbursed	Reimbursed	Appears to be reimbursed	Unknown	Does not appear to be reimbursed
Endobronchial lung volume reduction via unidirectional valves	Inpatient	Therapeutic procedure	Reimbursed	Reimbursed	Reimbursed	Reimbursed	Reimbursed
Occipital neurostimulation (ONS)	Inpatient	Medical device	Reimbursed	Not Reimbursed	Reimbursed	Reimbursed	Does not appear to be reimbursed

Treatment name[80]	Inpatient/ outpatient	Type of treatment	Reimbursement practice				
			Netherlands	Germany	France	England	Belgium
Sleep Position Trainer (SPT)	Outpatient	Medical device	Reimbursed	Not reimbursed	Unknown	Reimbursed	Does not appear to be reimbursed
Proton therapy	Inpatient	Therapeutic procedure	Reimbursed	Reimbursed	Reimbursed	Reimbursed	Reimbursed
Nervus hypoglossus stimulation	Inpatient	Medical device	Reimbursed	Reimbursed	Reimbursed	Not reimbursed	Appears to be less widely reimbursed
Autologous fat transplantation (AFT) for partial defects of the head/neck area	Inpatient	Therapeutic procedure	Reimbursed	Reimbursed	Appears to be reimbursed	Unknown	Not reimbursed
Repetitive Transcranial Magnetic Stimulation (rTMS) in depression	Intra- and outpatient	Therapeutic procedure	Reimbursed	Less widely reimbursed	Not reimbursed	Reimbursed	Less widely reimbursed
Implantable cardiac defibrillator (ICD)	Inpatient	Medical device	Reimbursed	Reimbursed	Reimbursed	Reimbursed	Reimbursed
Negative pressure wound therapy	Intra- and outpatient	Therapeutic procedure	Reimbursed	Reimbursed	Reimbursed	Reimbursed	Reimbursed
Hyperbaric oxygen therapy (HBOT)	Inpatient	Therapeutic procedure	Reimbursed	Reimbursed	Reimbursed	Less widely reimbursed	Less widely reimbursed
Continuous glucose monitoring	Outpatient	Medical device	Reimbursed	Reimbursed	Reimbursed	Reimbursed	Reimbursed
Nitric oxide measurement in guiding asthma treatment	Intra- and outpatient	Diagnostic procedure	Reimbursed	Less widely reimbursed	Not reimbursed	Reimbursed	Not reimbursed
Role of Natriuretic Peptides in Diagnosing Heart Failure	Intra- and outpatient	Diagnostic procedure	Reimbursed	Reimbursed	Unknown	Reimbursed	Less widely reimbursed

Treatment name[80]	Inpatient/ outpatient	Type of treatment	Reimbursement practice				
			Netherlands	Germany	France	England	Belgium
Carpal tunnel syndrome release	Inpatient	Therapeutic procedure	Reimbursed	Reimbursed	Reimbursed	Reimbursed	Reimbursed
Knee distraction in adult patients younger than 65 years with end-stage knee osteoarthritis	Inpatient	Therapeutic procedure	Does not appear to be reimbursed	Reimbursed	Appears to be reimbursed	Not reimbursed	Not reimbursed
MammaPrint in early-stage breast cancer	Inpatient	Diagnostic procedure	Not reimbursed	Reimbursed	Not reimbursed	Not reimbursed	Reimbursed
Platelet-rich plasma injection(s) (PRP) in lateral epicondylar tendinopathy	Inpatient	Therapeutic procedure	Not reimbursed	Reimbursed	Not reimbursed	Not reimbursed	Not reimbursed
Anaesthetic pain control techniques (radiofrequency denervation) in chronic nonspecific low back pain	Inpatient	Therapeutic procedure	Not reimbursed	Reimbursed	Appears to be reimbursed	Appears to be reimbursed	Appears to be reimbursed
Adjuvant Hyperthermia Intraperitoneal Chemotherapy (HIPEC)	Inpatient	Therapeutic procedure	Not reimbursed	Reimbursed	Not reimbursed	Appears to be reimbursed	Appears to be reimbursed
Neuromuscular electrostimulation (NMES) in severe heart failure	Inpatient	Therapeutic procedure	Not reimbursed	Appears to be reimbursed	Appears to be reimbursed	Does not appear to be reimbursed	Not reimbursed
High altitude treatment in severe refractory asthma	Inpatient	Therapeutic procedure	Not reimbursed	Appears to be reimbursed	Appears to be reimbursed	Does not appear to be reimbursed	Not reimbursed

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

In a separate appendix (Appendix 4, formatted as a slide presentation), we overview the regulation of basic healthcare packages. The appendix also includes the findings for Sweden, even though we excluded Sweden from further analyses because of its non-restrictive regulation and regional differences. We have ordered the regulatory overviews by the basic healthcare package's level of restrictiveness, with Belgium being the most restrictive and Sweden the least restrictive.

Each country's overview comprises four informational slides:

1. A general overview of the country's healthcare system and curative-care coverage.
2. The main actors involved in curative-care reimbursement.
3. The criteria used and the HTA organisation's role in the decision-making process.
4. The decision-making process for determining the entry or exit of care types from the basic healthcare package.

We compiled these overviews via desk research, interviews and an additional consultation round with the interviewees.