HEALTH TECHNOLOGY ASSESSMENT AND REIMBURSEMENT OF MEDICAL DEVICES IN ENGLAND, FRANCE, AND GERMANY

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INTRODUCTION AND METHODS

- Medical devices are '*products, services or solutions that prevent, diagnose, monitor, treat and care for human beings by physical means*'.[1]
- In 2020, the European medical technology market was estimated to be worth approximately €140 billion, making it the second largest market after the US; Germany, France, and the United Kingdom have the largest share of the European medical device market at 25.6%, 14.7%, and 12.2%, respectively.[1]
- Several studies have highlighted the need for a more versatile approach in assessing the value of medical devices compared with pharmaceuticals.[2,3] Nevertheless, less than 10% of European countries have established distinct health technology assessment (HTA) processes for medical devices, and of those that have, information is often limited.[4]
- As understanding HTA and reimbursement processes is essential for the success of new medical devices,[4] the aim of this study was to evaluate the device assessment and reimbursement systems in the three largest European medical device markets: Germany, France and England.
- A comprehensive literature review was conducted to identify processes for the assessment of medical devices, clinical and economic evidence requirements, and implications for patient access in the three countries of interest.

RESULTS

ENGLAND

The NICE HTA programmes for medical devices

- In England, device reimbursement is less structured than for pharmaceuticals. Although an assessment is not compulsory, it is widely acknowledged that a positive recommendation for a device from the National Institute for Health and Care Excellence (NICE) can drive faster and more consistent product adoption by providing commissioners and healthcare providers with the confidence that the device provides an overall benefit to patients and the National Health Service (NHS).[5,6]
- The three NICE evaluation programmes applicable to medical devices are described in **Table 1**.[6-10]

Table 1. Overview of NICE HTA programmes for medical devices[6-10]

Programme	TAP	DAP	MTEP
Technologies assessed	Cost-incurring devices	Cost-incurring diagnostics	Cost-saving and cost-neutral devices and simple diagnostics
Clinical performance versus NHS SOC	Better		Better or non-inferior
Preferred evidence type*	Randomised-controlled trial data	End-to-end controlled trial data	Randomised-controlled trial data
Economic analysis method and threshold	**Cost-utility: £20-30,000 per QALY**		**Cost-comparison** that shows better or similar health benefits at similar or lower cost than comparators
Recommendations	• Recommended in specific circumstances • Recommendation only in a research context • Not recommended	• Recommended • Recommended in specific circumstances • Recommended with data collection • Recommendation only in a research context • Not recommended	
Funding mandate if recommended	✓	✘	

*NICE considers all evidence types in its evaluations, but has preferred sources depending on the specific use being considered.[7]

DAP, diagnostics assessment programme; MTEP, medical technologies evaluation programme; NHS, National Health Service; SOC, standard of care; TAP, technology appraisal programme

- As the vast majority of technologies assessed in the Technology Appraisal (TA) programme are pharmaceuticals, the main HTA programmes applicable to devices are the Diagnostics Assessment Programme (DAP) and the Medical Technologies Evaluation Programme (MTEP).[8]
- Consequently, devices and simple diagnostics must provide at least an equivalent health benefit to those currently used within the NHS whilst reducing costs or resource use for a NICE recommendation.

Reimbursement for medical devices in England

- Devices recommended through the DAP and MTEP programmes do not receive mandatory NHS reimbursement unless they meet the specific criteria laid out in the 2022/23 MedTech Funding Mandate policy. This policy mandates commissioners to fund devices that are:[12]
  - Clinically effective
  - Cost saving in three years (as assessed by NICE)
  - Affordable to the NHS (costs ≤£20 million).
- NICE-recommended devices ineligible for the funding mandate are only reimbursed when an individual (or group of) Clinical Commissioning Groups (CCGs) purchases them.[5]
- Although faster uptake has been shown with a NICE recommendation, many devices in the UK are sold directly to CCGs without undergoing an evaluation by NICE.[13]

FRANCE

- In France, the Haute Autorité de Santé (HAS) assess medical devices for individual use and for diagnosis, therapy or disability compensation, after the CE marking has been obtained.[14] Devices are assessed in the context of the indication for which they will be used.[14]
- Most devices are covered by Diagnosis Related Group (DRG) funding via the mandatory health insurance (MHI). Innovative or expensive devices need to be enlisted on the French LPPR [the list of products and services qualifying for reimbursement] for reimbursement by MHI.[15,16]
- Following market authorisation, an application must be made to the National Commission for the Evaluation of Medical Devices and Health Technologies (CNEDiMTS) and the Healthcare Products Pricing Committee (CEPS).[15,16]
- The Commission for Economic and Public Health Evaluation (CEESP) are consulted to provide an independent efficiency opinion if an economic evaluation is required.[15]
- The final decision for registration falls under the jurisdiction of the Ministry of Health.[15]
- If a medical device conforms with an existing LPPR generic line description, it doesn't need to go through a CNEDiMTS evaluation.[15]
- The timeline for submission of an application for reimbursement and the publication for inclusion in the LPPR is 180 days.[15]
- Outpatient devices linked to a procedure are not subject to an individualised pricing structure but are included in the fee of a procedure.[15]

Clinical added value assessment

- CNEDiMTS issues an opinion on:[15]
  - the clinical benefit (SMR) of the device based on several factors including its efficacy, safety, and the unmet need, and
  - the clinical added value (ASMR) of the device based on the ability to meet the unmet need and the impact on the healthcare system.

Table 2. Classification of ASMR for medical devices[15]

Clinical benefit (SMR) *Equates to the rate of reimbursement*	Clinical Added Value (ASMR) *Equates to the value of the drug*		
	Class	**Level**	**Description**
• **Important - 65%** • **Moderate - 30%** • **Mild - 15%** • **Insufficient - not reimbursed** **It considers several criteria including the severity of disease, the efficacy and safety, and therapeutic alternatives.**	Major	V	Demonstrate an appreciable mortality benefit compared with the appropriate comparator
	Important	IV	Demonstrate additional clinical benefit in terms of efficacy, risk reduction and/or quality of life compared with the appropriate comparator (ASMR level dependent on extent of additional benefit)
	Moderate	III	
	Minor	II	
	Absent	I	Demonstrate no additional clinical benefit compared with the appropriate comparator

Economic evaluation requirement

- Since October 2013, an economic evaluation has been a requirement of reimbursement submissions for medical devices that are deemed to be innovative and are likely to either result in a significant impact on practice or on MHI expenditure.[17]
- From the 1st January 2023, HAS are set to change the specific criteria used to assess whether such products require a health economic (HE) evaluation.[18]
- **A HE evaluation will be required if:[18]**
  - The forecast sales ≥€20 million per year excluding tax, or if the company claims an impact on the organisation of care, professional practices or the conditions of patient care
  - The product is an advanced therapy medicinal product.
- **A HE evaluation will be not be required if:[18]**
  - The product is indicated for an adult population and is being extended to a paediatric population
  - The forecasted increase in the patient population for an indication extension is <5% over 2 years
  - The product is not protected by a patent or supplementary protection certificate.

GERMANY

In Germany, medical device reimbursement fundamentally differs from pharmaceuticals as medical devices are evaluated within the context of their associated diagnostic or treatment method. In addition, the pathway to reimbursement depends on whether the device will be used in a hospital (inpatient) or ambulatory (outpatient) setting.[19]

Inpatient setting

- As in many European countries, inpatient devices are reimbursed according to DRG coding.[20] The German DRG classification system uses case related coding rules that apply to diagnoses (International Classification of Diseases [ICD]-10 German modification) and procedures (Operations and Procedure Codes [OPS]).[19]
- If a new medical device is lower risk and part of an established method that already has an established DRG code, it will be reimbursed immediately without a formal assessment by the German Institute for the Hospital Remuneration System (InEK) and The Federal Joint Committee (G-BA).[19]
- If the new medical device is considered high-risk and cannot be associated with an existing DRG code, then the device is subject to a 'New examination and treatment methods' (NUB) HTA assessment by both InEK and the G-BA.[20,21]
  - The procedure determines whether there is an additional benefit, the potential for an additional benefit or no additional benefit compared with established procedures and devices.[21]
  - In addition, the procedure assesses the number of patients being treated with it, the additional costs associated with staff and materials, and the reason why costs are not yet appropriately covered by existing DRG tariffs.[22]
  - Reimbursement from statutory health insurers (the GKV) is only granted if there is an additional benefit – if there is a potential benefit, an investigative trial assessing the benefit over the comparator must be conducted.[21]
  - The NUB procedure takes approximately 2 years.[23]

Outpatient setting

- In the outpatient setting, any innovative diagnostic or therapeutic method must be evaluated prior to reimbursement. This may include an assessment from the G-BA to determine that the method has a benefit for patients, is required, and is economical.[19]
- If the G-BA determine the method to have an additional benefit, then by law it must reimbursed by the GKV.[19]
- As a result, medical devices are not automatically reimbursed by the GKV unless they are connected to a recognised therapy or treatment method.[20]
- Consequently, private health insurers play a large roll in the reimbursement of medical devices used in the outpatient setting.[19,20]

The G-BA's assessment criteria for outpatient and/or inpatient care

The G-BA's criteria for assessing a diagnostic or therapeutic method described in **Table 3**.[24,25]

Table 3. The G-BA's assessment criteria for outpatient and/or inpatient care[24,25]

Criteria	Aspects considered
Medical Necessity	• Natural history of disease • Unmet need • Available diagnostic or therapeutic alternatives
Benefit	• Efficacy via patient-relevant endpoints (morbidity, mortality, HRQoL) • Risk and side effects • Therapeutic consequence (if diagnostic)
Cost-effectiveness	• Cost estimate per patient • Cost-benefit analysis (including follow-up costs) in relation to the individual patient and in relation to all insured persons • Cost-benefit analysis compared to other diagnostic or therapeutic alternatives

GBA, The Federal Joint Committee; HRQoL, health-related quality of life

CONCLUSIONS

Summary	England	France	Germany
Assessment context	Device itself	In the context of the diagnostic or treatment method the device is associated with	
Funding	No funding mandate	Devices are funded if connected to a DRG code	
Clinical evidence	Robust evidence, e.g., RCT		
Economic evidence	Cost utility analysis*	Cost-effectiveness analysis	Cost-benefit analysis
Timeline	38 weeks	180 days	2 years if NUB is required; immediately if associated with DRG code

*For the Technology Appraisal and Diagnostic Appraisal Programmes – the medical technologies evaluation programme utilises a cost-comparison method. DRG, Diagnosis Related Group (DRG); NUB, New examination and treatment methods; RCT, randomised controlled trial

REFERENCES

1. MedTech Europe. The European Medical Technology Industry in figures [Internet]. 2021.
2. Drummond M, et al., Economic evaluation of medical devices and drugs—Same or different? Value Heal. (2009) 12:4733.
3. Iglesias CP. Does assessing the value for money of therapeutic medical devices require a flexible approach? Expert Rev Pharmacoeconomics Outcomes Res. (2015) 15:21–32.
4. Blüher M, et al., Critical Review of European Health-Economic Guidelines for the Health Technology Assessment of Medical Devices. Front Med. (2019) 6:278.
5. The AHSN Network. MedTechlandscape review [Internet]. 2019.
6. Remap Consulting. Medical Device Market Access: What are the pro's and cons of seeking NICE approval using the Medical Technologies Evaluation Programme? [Internet]. 2019.
7. NICE. NICE health technology evaluations: the manual [Internet]. 2022
8. NICE. Diagnostics Assessment Programme manual [Internet]. 2011.
9. NICE. Medical technologies evaluation programme methods guide [Internet]. 2017.
10. NICE. Guide to the methods of technology appraisal [Internet]. 2013.
11. Gibson S, et al., PP206 Health Technology Assessment Guidance In The United Kingdom: Addressing Issues Specific To Medical Devices. International Journal of Technology Assessment in Health Care. (2021) 37(S1):26–26.
12. NHS. MedTech Funding Mandate policy 2022/23 [Internet]. 2022.
13. Leng G, et al. Uptake of medical devices approved by NICE. BMJ Innov. (2018) 4(4):178–84.
14. HAS. Understanding medical device evaluation [Internet]. 2021.
15. HAS. Assessment principles established by the Medical Device and Health Technology Evaluation Committee (CNEDiMTS) to determine the reimbursement eligibility of medical devices for individual use [Internet]. 2019.
16. HAS. Medical device reimbursement in France [Internet]. 2020.
17. HAS. Methods for health economic evaluation [Internet]. 2015.
18. HAS. Decision relating to the significant impact on health insurance expenditure triggering the medico-economic evaluation of innovative health products [Internet]. 2022.
19. AiM. Reimbursement of Medical Devices in Germany 2020/2021 [Internet]. 2020.
20. AiM. Medical device reimbursement - important aspects on the German market [Internet].
21. AiM. Health technology assessment (HTA) [Internet].
22. Med Device Online. Overcoming Funding Challenges For Innovative Medtech In Germany Learnings From The NUB Process [Internet]. 2021.#
23. German Market Access Simplified. NUB method assessments in Germany [Internet].
24. The Federal Joint Committee (G-BA). Evaluation of new examination and treatment methods for outpatient and/or inpatient care [Internet].
25. The Federal Joint Committee (G-BA). Information sheet: Procedural and methodical requirements for the evaluation of a treatment method [Internet]. 2013.

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