Access to coverage with evidence development schemes for medical devices and procedures in England, France, Germany, Spain, and the USA

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Introduction

Manufacturers of medical devices (MDs) and medical procedures (MPs) must satisfy the requirements of regulatory authorities, health technology assessment (HTA) agencies, and local payers in order to achieve successful market access (1); however, each stakeholder has different evidentiary standards, and collecting clinical and economic evidence is time consuming and costly (2). As the evidence base may be limited at the time of market entry, MDs and MPs are potentially good candidates for coverage with evidence development (CED) schemes. CED schemes are typically used to support data collection to reduce uncertainty around the clinical or cost effectiveness of an MD or MP and inform future decisions about coverage or intended use (3).

Objectives

The objective of this research is to provide an overview of access to CED schemes for MDs and MPs in England, France, Germany, Spain, and the USA, and to address three key questions:

1 Do national HTA and payer agencies have a CED scheme for MDs or MPs?

2 What are the eligibility criteria to enrol onto a CED scheme?

3 How many MDs and MPs were enrolled onto each CED scheme in 2023?

Methodology

A targeted literature review of national payer and HTA agency websites was conducted to identify CED schemes and the eligibility criteria for enrolling MDs or MPs in the following markets: England (National Institute for Health and Care Excellence [NICE]), France (Haute Autorité de Santé [HAS]), Germany (Gemeinsamer Bundesausschuss [G-BA]), Spain (Red Española de Agencias de Evaluación de Tecnologías Sanitarias [RedETS]), and the USA (Centres for Medicare & Medicaid Services [CMS]).

CEDs were analysed for the number of MDs/MPs enrolled in schemes in 2023. Of those identified, CEDs were evaluated for the following elements: timing of application to scheme, priority areas, positive selection criteria, and possible outcomes following conclusion of the CED scheme.

Results

	HTA/payer body	CED scheme	Timing of application	Priority area(s)	Eligibility criteria	Outcomes (after CED conclusion)	Number of MDs/MPs enrolled in 2023
(4-7)	NICE	EVA	Early development – post-launch	Potential for clinical, system, or service user benefit in a priority area (mental health, cardiovascular, early cancer detection, technologies that boost healthcare capacity)	• CE or UKCA marked • Benefit to patients and healthcare system in area of national unmet need • Support from healthcare professionals and healthcare system • Need for evidence generation to support use in the NHS	• Early use in the NHS • Full NICE assessment following evidence generation	8
(8, 9)	HAS	Innovation funding (Forfait Innovation)	Early development	Innovative technologies	• Innovative • Early data supporting significant clinical benefit or reduction in healthcare spending • Meets an unmet medical need • The proposed protocol must be feasible and able to gather missing data on the clinical benefit	Traditional market access assessment for medical devices	2
(10, 11)	G-BA	Testing studies (Erprobungsstudie)	Early development	Potentially beneficial methods	• Sufficient evidence of potential benefit (effective, less complex, less invasive, or fewer side effects), but requires further data to support routine use • Potential to optimise the care pathway	• Full benefit assessment • Decision whether to include/exclude as an SHI benefit	2
(12-16)	RedETS	MS (estudios de monitorización)	Post-launch phase	• Uncertainty surrounding technologies' effectiveness or efficiency • Foreseeable high economic or organisational impact • Unknown behaviours in specific population groups	• Included in benefit package of the SNS • Demonstrates lack of evidence in one or more of the following areas: population/end users; technology; safety/adverse effects; organisation/costs and other implications	• Maintain inclusion on benefit package • Modifying conditions of use • Exclusion from public funding • Restricted to selected centres • Recommendation of reorganisation of resources	0
(17, 18)	CMS	TCET	Post-FDA market authorisation	• FDA-authorised medical devices with Breakthrough Device designation • High impact devices meeting Medicare population needs	• Provides more effective treatment or diagnosis of life-threatening or debilitating conditions • The device must either have no approved alternatives or offer a significant advantage over alternatives (e.g. reduces hospitalisation, improves quality of life, facilitates self-care, establishes long-term clinical effectiveness); availability is in the best interest of patients	National coverage by Medicare for 4 years, after which, the device could transition to post-TCET coverage if sufficient evidence supports its continued use	0† If TCET is implemented, CMS plan to enrol five FDA-designated breakthrough devices per annum

† CMS has proposed but not implemented TCET.

Conclusion

The national HTA agencies in England, France, Germany, and Spain have all implemented CED schemes for MDs/MPs (3-6, 8-15, 18). In the USA, CMS has proposed but not yet implemented Transitional Coverage for Emerging Technologies (TCET) as a CED scheme (7, 17). CED schemes present an opportunity for MD/MP manufacturers with insufficient data or an inability to manage large-scale clinical trials the possibility to launch while working towards future coverage; however, this research has demonstrated that access to CED schemes proved challenging, with very few MDs/MPs enrolled in CED schemes in 2023. An interesting extension to this research would be to analyse the outcomes for MDs/MPs following the conclusion of the CED scheme.

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Abbreviations

CE, conformité européenne
CED, coverage with evidence development
CMS, Centers for Medicare & Medicaid Services
EVA, Early Value Assessment
FDA, Food and Drug Administration
G-BA, Gemeinsamer Bundesausschuss
HAS, Haute Autorité de Santé
HTA, health technology assessment
MD, medical device
MP, medical procedure
MS, Monitoring Studies
NHS, National Health Service
NICE, National Institute for Health and Care Excellence
RedETS, Red Española de Agencias de Evaluación de Tecnologías Sanitarias
SHI, Statutory Health Insurance
SNS, Sistema Nacional de Salud
TCET, Transitional Coverage for Emerging Technologies
UKCA, United Kingdom Conformity Assessment