DTx REGULATORY & REIMBURSEMENT PATHWAYS

DIGITAL THERAPEUTICS ALLIANCE

ENGLAND Regulatory

DTx products in England are mostly regulated as medical devices, depending on their function and complexity. Guidelines are available here. Different regulations apply to Great Britain and Northern Ireland. This factsheet covers England only, although the regulatory section is also applicable to Wales and Scotland.

Category Name	Medical Device
Conformity Assessment	CE Mark granted by a designated EU Authorized Notified Body UKCA Mark granted by a UK-designated Approved Body UK Approved Bodies can only issue UKCA marks, not CE marks. In practice, the same organisations may be designated both as a Notified Body and an Approved Body
Responsible Regulatory Agency	Medicines and Healthcare products Regulatory Agency (MHRA)
Products that Qualify For Regulatory Review	DTx manufacturers must determine the risk classification of their device based on the regulations. The MDCG guidelines support interpretation of the EU MDR. The MEDDEV guidance is designed to support interpretation of the previous EU MDD, and therefore may be helpful for interpretation of the UK MDR. Class I products do not qualify for regulatory review by a notified body. The manufacturers self-declare conformity to the MDR and assign the CE label themselves. *Products that qualify for regulatory review include:* • Class IIa: It is anticipated that most DTx software will fall under this classification in the future. • Class IIb: Includes DTx products with higher risks or consequences. • Class III: No Class III DTx products currently exist, but this is possible in the future. UKCA Mark requirements (to be updated in due course) are contained in UK MDR 2002, derived from previous EU regulations (EU Medical Devices Directives). There is some divergence with the CE mark as the EU now has adopted EU MDR / IVDR, although future changes to UKCA may mean that divergence will likely be reduced.
Pre-Submission Opportunities	No formal process exists, but manufacturers can submit specific questions to the MHRA Innovation Office.
Guidelines To Be Met	UKCA Mark requirements (to be updated soon) are still derived from the EU CE Mark regulations. UKCA marking is specifically intended for products sold in Great Britain (England, Scotland, and Wales). Northern Ireland does not recognise the UKCA Mark. It serves as a certification that the product complies with regulatory standards in Great Britain. Guidance is available here: Medical devices: conformity assessment and the UKCA mark
Other Guidelines	The Digital Technology Assessment Criteria (DTAC) brings together legislation and good practice in the areas of clinical safety, data protection, technical security, interoperability and usability and accessibility standards. It sets out the expected standards for suppliers seeking to enter the NHS. It is not currently a regulation in law although some components are legal requirements. It is considered good practices and NHS will expect to see compliance with DTAC.
Product Recognition	CE Mark (until June 2030 depending on device type and classification) UKCA Mark (since January 2021)
Approximate Timing For Process Completion	For CE mark: 12–18 months, although the timeline is currently extended due to the limited number of notified bodies. For UKCA mark: Similar to CE mark for products of the same risk class Engaging with a competent consultant or regulatory expert can help streamline the process and address any challenges that may arise.
Cost	For CE mark: cost is dependent on internal regulatory expertise and capacity. For UKCA mark: cost is dependent on internal regulatory expertise and capacity.

ENGLAND Reimbursement

Prescription Required?	There is no formal mechanism for prescribing DTx equivalent to the British National Formulary for medicines. DTx that are procured by NHS commissioners or trusts may be offered to eligible patients as standalone interventions or as part of a wider package of care.
Public Insurance Coverage	Around 85% of healthcare expenditure in the UK is via the National Health Service (NHS), which is taxpayer-funded and free at the point of use for all citizens. Healthcare is devolved, with in practice four health systems in England, Scotland, Wales and Northern Ireland. This fact sheet covers England only. Currently there is no national market access pathway that leads to reimbursement for DTx products. In England, NHS organizations play a dominant role in commissioning and funding DTx products. There are 42 Integrated Care Systems (ICSs) in the NHS, bringing together providers and commissioners of health and care services in their respective areas. Key decision-making organizations within ICSs are: • Integrated Care Boards (ICBs), which commission most health services and replaced Clinical Commissioning Groups (CCGs) in 2022 • Primary Care Networks (PCNs), which bring together groups of GP practices to help coordinate and delivery local services • Foundation Trusts and NHS Trusts, which provide healthcare services to patients There are a number of relevant initiatives aimed at increasing the adoption and spread of well-evidenced, beneficial DTx: • The NHS Innovation Service provides a one-stop shop for support and guidance for innovators. The National Institute for Health and Care Excellence (NICE, UK's HTA body) has published a framework for the assessment and evaluation of digital health technologies. • NICE has introduced Early Value Assessment (EVA) for medtech, including DTx, which addresses an unmet need in the NHS. EVA assesses the available evidence and may offer a conditional recommendation for use in the NHS while further evidence is gathered. • The NHS Innovation Accelerator supports the spread of promising innovations within the NHS • Health Innovation Networks (HINs) exist to help the adoption and spread of innovation within their respective areas, and may be able to offer some guidance and support.
Private Health Insurance	Private insurance represents a smaller segment, accounting for 15% of total healthcare expenditures. Reimbursement agreements with private health insurers have not experienced strong uptake, although some products are partially covered.
Employer-Sponsored Healthcare	Relatively uncommon but may become more relevant in the future.
Consumer-Funded	Low willingness for consumers to pay out-of-pocket. Relatively small market but there could be potential for growth in the future.

Note: This document represents pathways that continue to evolve. It does not provide legal advice.