# DTx REGULATORY & REIMBURSEMENT PATHWAYS

DIGITAL THERAPEUTICS ALLIANCE

## FRANCE Regulatory

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| **Category Name** | Medical Device |
| **Conformity Assessment** | CE Mark granted by a designated Authorized Notified Body or self-declared by the manufacturer in the case of lower risk class devices (risk class I) |
| **Responsible Regulatory Agency** | National Agency for the Safety of Medicines and Health Product (ANSM)<br>Authorized Notified Bodies (2 in France as May 2024) |
| **Products that Qualify For Regulatory Review** | DTx manufacturers complete a self-assessment risk classification (according to this MDCG guideline) to determine how the CE Marking is carried out.<br>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.<br>Products that qualify for regulatory review include:<br>• Class IIa: It is anticipated that most DTx software will fall under this classification in the future.<br>• Class IIb: Includes DTx products with higher risks or consequences.<br>• Class III: No Class III DTx products currently exist, but this is possible in the future. |
| **Pre-Submission Opportunities** | No process exists. |
| **Guidelines To Be Met** | Key systems:<br>• Company-wide quality management system (QMS) according to MDR article 10, compliant with ISO 13485 and product-specific technical documentation (MDR annex II and III, covering IEC 62304, IEC 62366, and ISO 14971).<br>• Clinical evaluation report according to MDR Article 61 (annex XIV and XV), MDCG, and MEDDEV 2.7<br>• Post-market surveillance report according to MDR Article 85 for Class I and Article 86 for Class IIa, IIb, and III.<br>Personnel requirements:<br>• Minimum of one Person Responsible for Regulatory Compliance (PRRC) and one Medical Device Consultant.<br>• Manufacturers not registered in the EU must appoint an Authorized European Representative.<br>Full regulation: MDR 2017/745 |
| **Other Guidelines** | CE Mark applies to all European countries at this time, but DTx product documentation and labelling must be translated into French.<br>Significant changes to the software may require a re-certification by the responsible authority.<br>General Data Protection Regulation (GDPR) compliance is required; data hostage within the EU is necessary due to a currently invalid EU-US data privacy shield.<br>Notes:<br>• Class I products need to fulfill the same guidelines as higher risk classes, but do not need to involve a notified body.<br>• DTx product may be recognized as a connected medical device; this is established after CE Marking, but before reimbursement. |
| **Product Recognition** | CE Mark |
| **Approximate Timing For Process Completion** | For CE Mark: 12–18 months, although timeline is currently extended due to the limited number of notified bodies.<br>Registering CE mark with ANSM: 2–3 weeks. |
| **Cost** | Cost dependent on product and company size, as well as internal regulatory expertise and capacity.<br>No fee for registering CE mark with the ANSM. |

# DTx REGULATORY & REIMBURSEMENT PATHWAYS

## FRANCE Reimbursement

**Prescription Required?**

Reimbursed digital medical devices are prescribed.

**Public Insurance Coverage**

In 2023, France introduced a dedicated reimbursement pathway for Digital Medical Devices including remote patient monitoring products (RPM) and products with a therapeutic intended purpose (DTx).

This document covers only the pathway for DTx products.

The National Commission for the Evaluation of Medical Devices and Health Technologies (CNEDiMTS) of the Haute Autorité de Santé (HAS) is the health technology assessment (HTA) body responsible for evaluating and recommending DTx products.

The Digital Health Agency (ANS) is responsible for the technical certification (security and interoperability).

Two paths exist:
DTx can pursue a reimbursement either via a fast-track process for new innovative technologies, via the PECAN pathway (Prise En Charge Anticipée Numérique) with a one year non renewable reimbursement or via the Common Law (Droit Commun) pathway for technologies demonstrating mature and sufficient clinical value.

**Permanent LPPR (List of Products and Services qualifying for reimbursement)—Reimbursement under the Common Law**

DTx presenting sufficient and robust clinical and organizational benefits can obtain a reimbursement for a period of 5 years, with possibility of renewal.

These products have to previously go through the ANS technical certification, they are then evaluated by the CNEDiMTS.

This pathway is reserved to mature technologies that have already conducted their clinical trials, either after a PECAN procedure or are just introducing the technology in the French healthcare scheme.

The final LPPR listing price is negotiated with CEPS (economic committee for health products).

**Preliminary Listing - PECAN a fast-track procedure introduced for innovative DMD**

The early coverage pathway allows a one-year early coverage for DTx meeting prerequisites, then DTx can apply for regular LPPR listing.

To apply for the PECAN pathway, DTx manufacturers can submit their ANS technical certification application in parallel with their CNEDiMTS evaluation.

The one-year transitional reimbursement is a predefined fixed compensation, by patient for all indications

- Initial fee (1st quarter): 435 €
- Then 38,3 € per month from 4th month
- Total: 780 € max per year

Towards a permanent DTx reimbursement, the manufacturer must provide the final submission at the end of the first 6-month of PECAN.

The final LPPR listing price is negotiated with CEPS.

There are also experimental coverage options:

- Article 51: Article 51 is an article of the French Social Security Financing Law of 2018 setting a new framework for launching experiments of a limited duration. Conditions of eligibility include product innovation, feasibility, ease of distribution, and price to quality ratio.
- Innovation Funding (forfait innovation): Exceptional limited time funding, ahead of coverage by the mainstream health system to conduct a clinical or medico-economic study.

**Private Health Insurance**

Private health insurance accounts for 7% of total healthcare expenditures. 95% of the population has some form of private, voluntary insurance to cover costs such as copayments for drugs, glasses, and dental health.

**Employer-Sponsored Healthcare**

Not common.

**Consumer-Funded**

Low willingness for consumers to pay out-of-pocket.

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