

# The French PECAN assessment and reimbursement model

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# Permanent reimbursement models in France

- **Digital Therapeutics (DTx):**
  - *LPPR* (Liste des produits et prestations remboursables)
  - Applications classified as medical devices (all risk classes)
- **Remote Patient Monitoring (RPM):**
  - *LATM* (liste des activités de télésurveillance médicale)
  - Applications classified as medical devices (all risk classes)

# PECAN

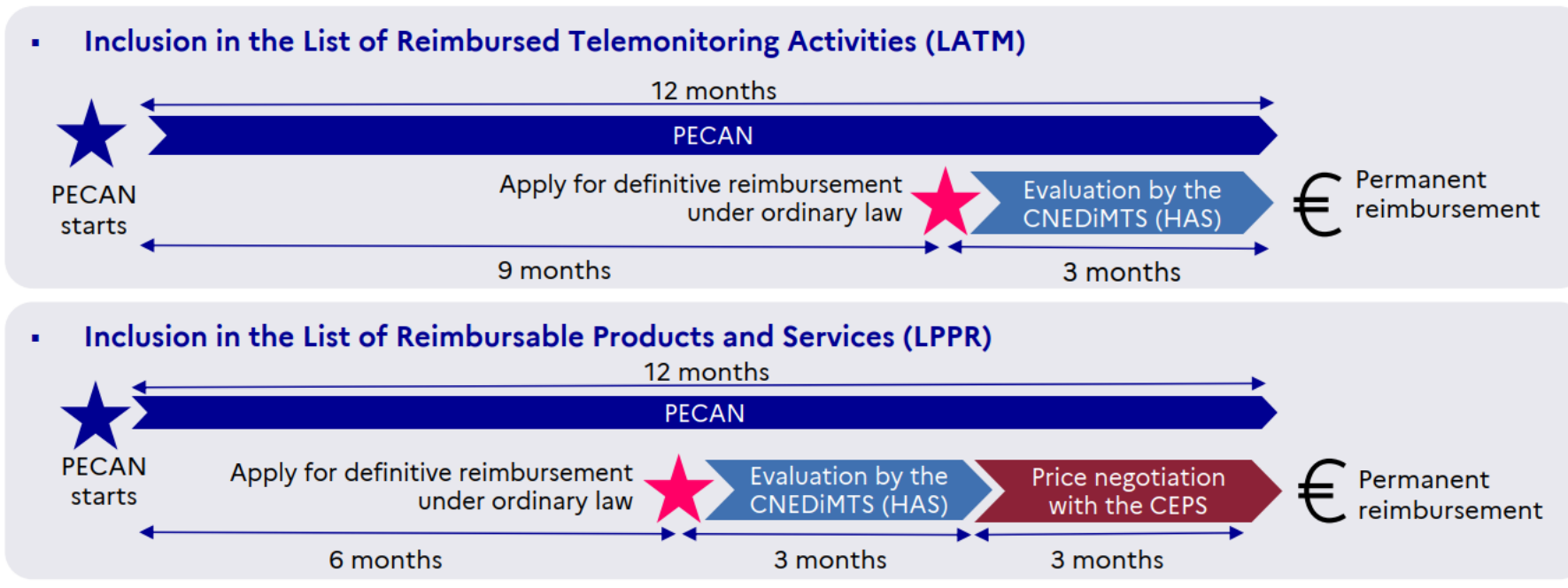
- In addition to these permanent reimbursement models for DTx and RPM solutions, LPPR and LATM, France introduced the Prise en charge anticipée numérique (**PECAN**) reimbursement model in April 2023
- The PECAN process is intended for DHTs that show **potential benefits**, but for which there is **not yet sufficient evidence** to qualify for permanent LATM or LPPR registration.
- The development of the PECAN model was inspired by the Fast Track (DiGA) process in Germany

# PECAN

- The PECAN includes ***one-year temporary reimbursement*** access schemes for DTx and RPM solutions in accordance with the ***Social Security Funding Law 2022, Article 58***
- During the one-year temporary reimbursement there is predefined ***fixed compensation*** for DTx and RPM
- After 9 months, ***price negotiations*** for ***DTx*** products will commence
- After 12 months, ***RPM*** solutions will have ***fixed prices***

# PECAN timeline

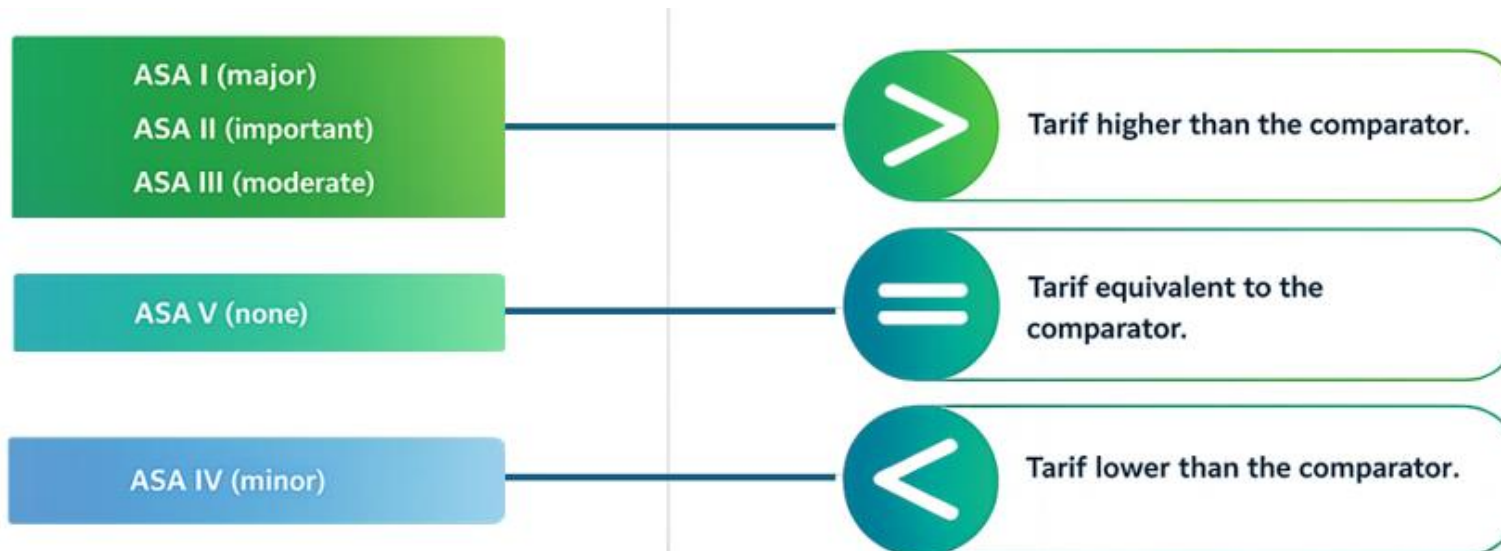
## PECAN – after a year of reimbursement



# Permanent reimbursement of DTx

- The level of **added value (ASA)** has an impact on pricing
  - The expected **added value** is defined as the improvement achieved by the new technology **compared to the reference treatment**

*Added value relative to the reference treatment*



# PECAN assessment process domains

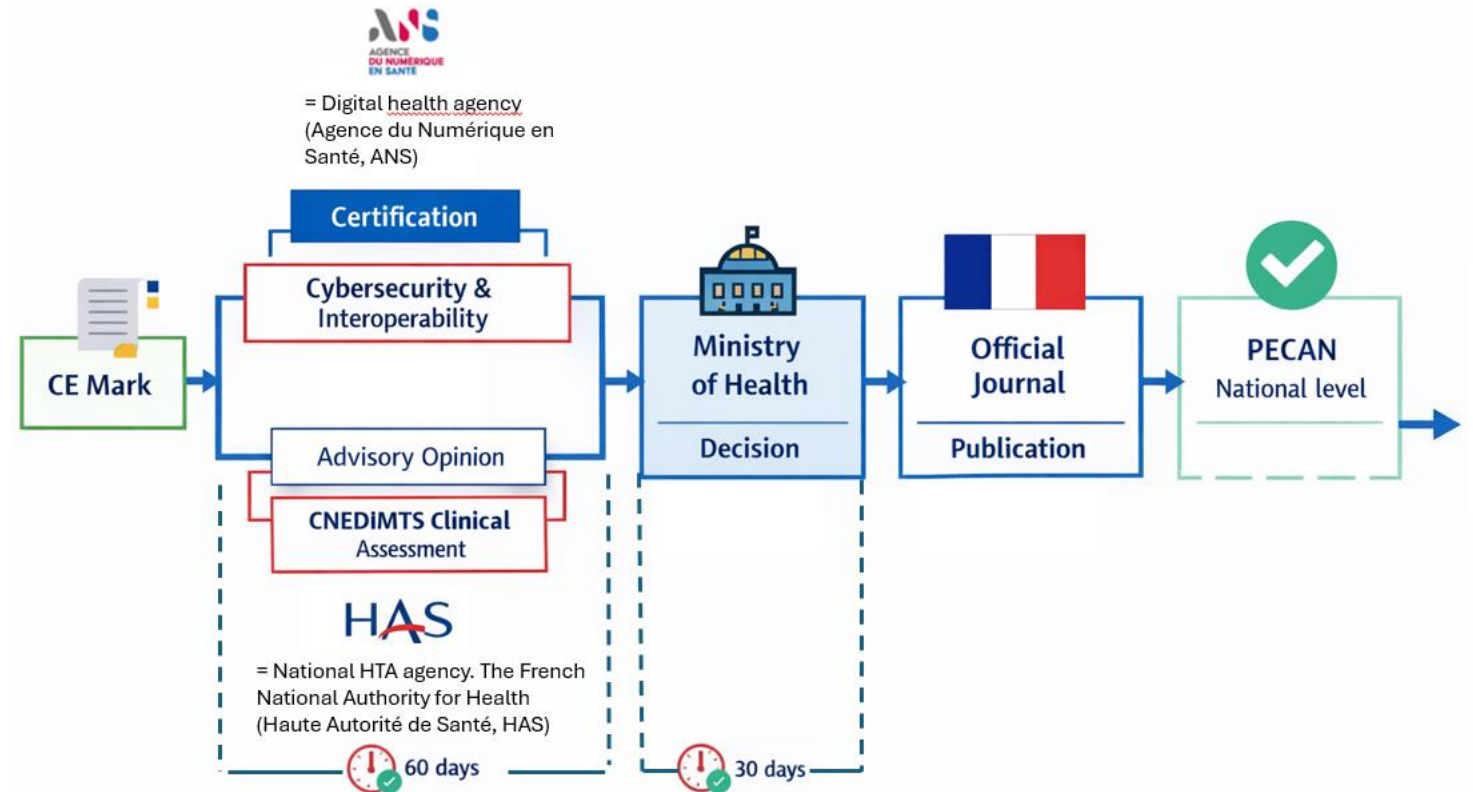
- ***Clinical assessments*** are conducted for all therapies
  - Flexible evidence requirements are applied, taking into account the specific characteristics of digital health, such as RCT-studies not always being mandatory and organizational impacts also being considered where relevant
- ***Economic assessments*** (modeling and budget impact) are only carried out if a high added value score and significant impact on health spending are claimed
- ***Data security and protection***
- ***Interoperability***
- ***Artificial intelligence (AI)***-specific criteria are available for products that utilize AI

# Acceptable evidence in the PECAN assessment process

- Only a limited set of scientific and organizational evidence is accepted as scientific evidence
  - **Accepted:** evidence-based clinical guidelines, HTA reports, systematic literature reviews and meta-analyses, clinical studies, and studies assessing organizational impact
  - **Not accepted:** abstracts, posters, conference presentations, theses, expert endorsement letters, preclinical studies, or general narrative articles, editorials, or opinion pieces.
  - **Studies conducted in France are preferred** in the assessment; however, international studies are also accepted, provided that their transferability to the French healthcare context is adequately justified.

# PECAN Process

- The parallel assessment process:
  - **ANS** assesses data security and protection as well as interoperability aspects
  - **HAS** assesses clinical benefit as well as, on a case-by-case basis, organizational and economic benefit
- The **Ministry of Health** makes the reimbursement decision based on the assessments conducted by ANS and HAS
- Reimbursement is provided through the National Union of Health Insurance Funds (**UNCAM**, Union Nationale des Caisses d'Assurance Maladie).



Modified from: Ouassim NAIET EL GAIED, PECAN, the new DiGa-like pathway in France

# Products approved through the PECAN process and permanent reimbursement pathways

- Approved products through the PECAN process. Statistics from April 2023 to March 2025
  - All three approved applications have been RPM solutions.
  - One DTx (Ludocare), intended for the treatment of childhood asthma, has now received a positive assessment but has not yet obtained a reimbursement decision

Intention to apply	Initiated (submitted or not)	Approved	Fail	Withdrawn
42	17	3	6	1

- Permanent reimbursement pathways:
  - 45 RPM solutions through the LATM pathway
  - No DTx solutions through the LPPR pathway



**Thank You**

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