DECODING PECAN: WHAT EARLY FRENCH ASSESSMENTS REVEAL ABOUT MARKET ACCESS FOR DIGITAL MEDICAL DEVICES

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1. BACKGROUND AND OBJECTIVES

PECAN (*Prise En Charge Anticipée des dispositifs médicaux numériques*) is a temporary reimbursement pathway introduced in France in 2023 to support early market access and evidence generation for innovative digital medical devices.

➔ **To characterize the evidence expectations and decision drivers of PECAN assessments.**

➔ **To explore their relationship with subsequent reimbursement evaluations (LATM/LPPR).**

2. METHODS

Data source

All PECAN opinions published by the French National Authority for Health (HAS) between July 2023 and June 2026.

Inclusion

All digital medical devices evaluated under PECAN (telemonitoring solutions and digital therapeutics).

Data extraction and analysis

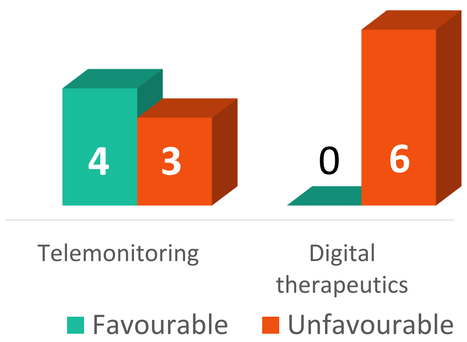
- PECAN decisions and rationale for favourable and unfavourable opinions
- Key elements highlighted by HAS
- Subsequent reimbursement assessments (LATM/LPPR) and outcomes
- Thematic analysis of decision drivers

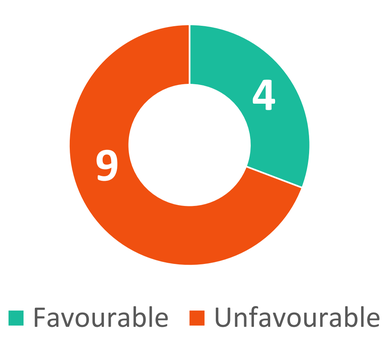
3. OVERVIEW OF PECAN ASSESSMENTS

13 PECAN evaluations

7 telemonitoring solutions

6 digital therapeutics



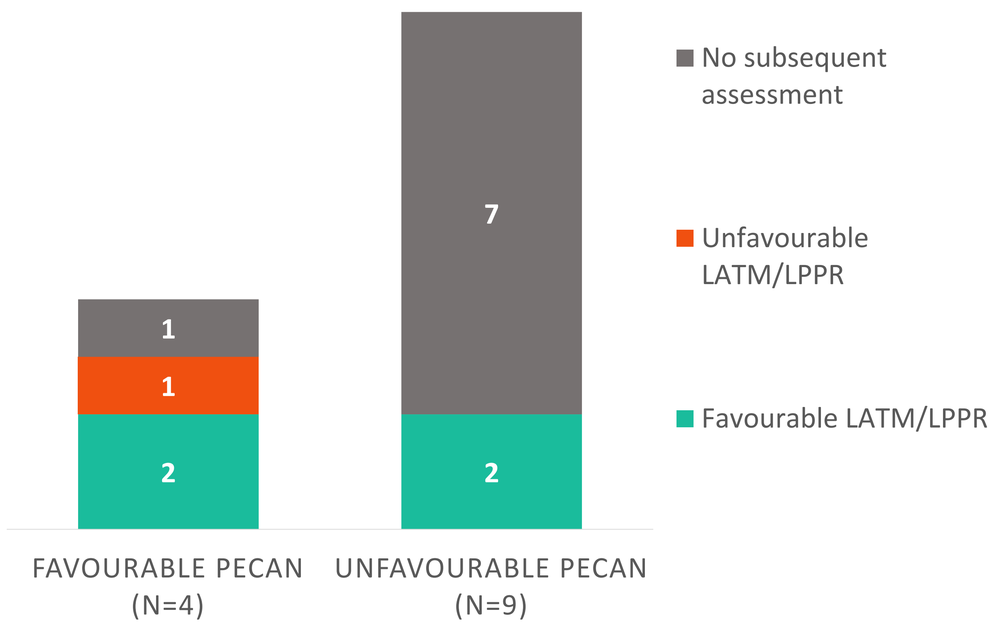


4. KEY DRIVERS OF PECAN DECISIONS

Assessment dimension	Factors associated with favourable opinions (main themes identified by HAS)	Factors associated with unfavourable opinions (main themes identified by HAS)
Clinical evidence	• Plausible clinical benefit • Preliminary product-specific data demonstrating expected outcomes	• Lack of product-specific evidence; Insufficient demonstration of clinical benefit • Evidence based on other solutions (limited transposability)
Methodological robustness	• Relevant comparator and outcome measures • Methodologically robust evidence	• Non-relevant comparator vs French standard of care • Short follow-up, small or non-representative samples • Methodological limitations in RCTs
Organisational impact	• Clearly identified organisational need • Plausible improvement in care pathways	• Organisational benefits not demonstrated • Mismatch between claimed activities and evidence
Evidence-generation strategy	• Credible plan for generating decision-relevant evidence for subsequent reimbursement	• Ongoing studies insufficiently mature; Results not expected within PECAN timelines • No additional studies planned
Alignment with reimbursement requirements	• Trajectory towards permanent reimbursement; Study design and population aligned with future LATM/LPPR expectations	• Evidence unlikely to meet LATM/LPPR requirements; Limited relevance for future reimbursement assessment

5. PECAN DECISION AND SUBSEQUENT REIMBURSEMENT ASSESSMENTS

Among the 13 devices evaluated under PECAN, 5 subsequently underwent a LATM/LPPR assessment (3 with an initial favourable opinion and 2 with an initial unfavourable opinion).



6. IMPLICATIONS FOR MARKET ACCESS STRATEGY

Strategic priority	Recommendation
✓ **Demonstrate organisational value**	Document unmet organisational needs and expected improvements in care pathways.
✓ **Generate product-specific evidence**	Provide preliminary device-specific data rather than relying on evidence from other solutions.
✓ **Anticipate permanent reimbursement**	Align evidence-generation plans and study timelines with LATM/LPPR requirements.
✓ **Ensure methodological robustness**	Use relevant comparators and outcomes, with adequate sample size and follow-up.

7. CONCLUSION AND KEY TAKEAWAYS

- PECAN appears to provide an early indication of reimbursement readiness, particularly regarding organisational value and evidence-generation strategies.
- Favourable PECAN opinions were associated with a clear organisational value proposition and a credible evidence-generation plan.
- Subsequent reimbursement assessment was more frequent following favourable PECAN opinions (3 of 4 devices vs 2 of 9).
- Favourable reimbursement outcomes were observed following both favourable and unfavourable PECAN opinions, highlighting that early access and permanent reimbursement assessments may lead to different outcomes.

1 Evidence from other digital solutions may be insufficient.

2 Demonstrate improvements in care pathways.

3 Align evidence-generation plans with LATM/LPPR requirements.

4 An unfavourable PECAN opinion does not preclude favourable reimbursement.



DTx, digital therapeutics; HAS, French National Authority for Health; LATM, List of Telemonitoring Activities; LPPR, List of Reimbursable Products and Services ; PECAN, Early Coverage of Digital Medical Devices; TM, telemonitoring.

COI: Gaugy P et Le Mao J are employees at CEMKA, one of the first French consulting firms in the field of evaluation of products, programs and organizations in Health. The study was not sponsored.