The French Transitional Coverage Pathway (PECT) for Innovative Therapeutic Medical Devices: a four-year retrospective analysis

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Context & Objectives

- The "*Prise En Charge Transitoire*" (PECT) was introduced in 2021 to enable early coverage of innovative therapeutic medical devices (MDs) while collecting missing data for listing under standard scheme (LPPR).
- To qualify, the HAS (French HTA body) must confirm that all eligibility criteria are met. Within 12 months of PECT request, manufacturers must submit an LPPR listing application. PECT coverage may be renewed once and remains active during the LPPR assessment (HTA then price negotiation), ensuring uninterrupted patient access.

Method

This study analyzes all available public data on the 13 devices assessed by the HAS for PECT listing, including their subsequent associated procedure creation and standard listing (via LPPR). Data are collected until October 28th, 2025.

Results

Among 6 MDs approved by the HAS for PECT listing:

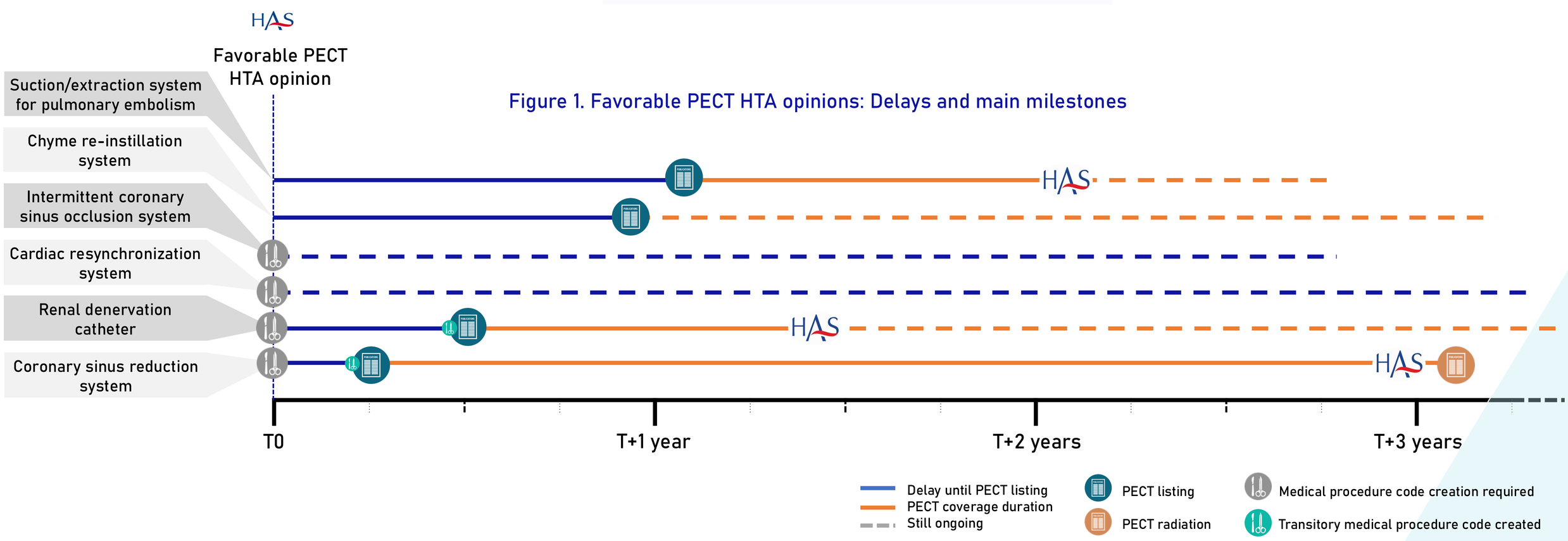
- 4 gained effective PECT listing.
- 2 remain pending after more than 34 and 40 months, likely due to missing medical procedure codes.
- Paradoxically, 2 PECT-listed devices requiring procedure code creation had the fastest listings.

All 4 PECT-listed MDs later submitted LPPR dossiers:

- Only 2 received favorable opinions from HAS. Their added-value were low to moderate (ASA levels III/IV and III).
- These results suggest that the high added value expected at PECT entry is not consistently confirmed in later evaluations.

- No MD has yet transitioned from PECT to LPPR listing.
- Meanwhile, PECT coverage continues, with durations ranging from 21 to 34 months (still ongoing), exceeding the initial 12-month target, and raising questions about efficiency.

Figure 1. Favorable PECT HTA opinions: Delays and main milestones



7 MDs were rejected by the HAS for PECT listing:

Table 1. Unfavorable PECT HTA opinions: Eligibility criteria assessment and subsequent LPPR listing HTA opinions

Medical device	Severe and/or rare disease or compensation for a disability	No relevant comparator / no relevant therapeutic alternative	Significant improvement in clinical status or disability compensation	Innovation, novelty character	Clinically relevant efficacy and acceptable potential adverse effects	Ability of the ongoing study to cover the evidence gap within 12 months
Orthokeratology lenses with peripheral myopic defocus	N	N	Y	N	Y	X
Digital psychotherapy	Y	Y	N	Y	N	X
Aortic stent used in type I dissections according to DeBakey classification	Y	Y	N	Y	N	X
Mitral contour system	Y	Y	N	Y	N	X
Device for percutaneous arterialization of the deep venous network	Y	Y	N	Y	N	X
Hip orthosis	Y	Y	N	Y	N	N
Thoracic branch endoprosthesis	Y	N	N	N	N	Y

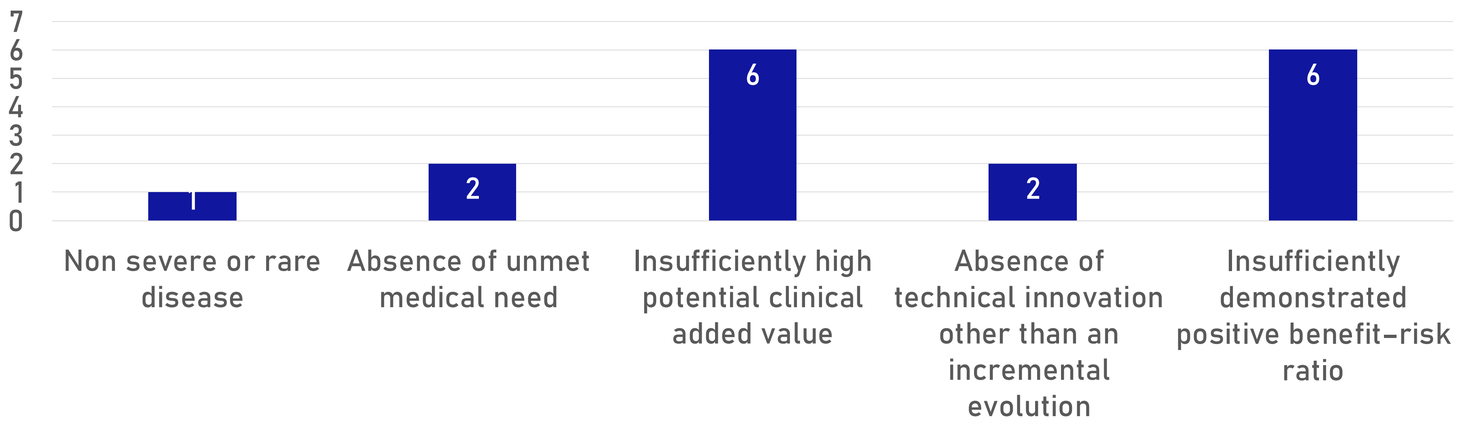
- These 3 MDs later received LPPR listing opinions : 2 favorable but with low to no added-benefit (ASA levels V and IV) and 1 unfavorable.
- No predictive pattern for LPPR success or failure after PECT rejection.

Y : validated ; N : not validated ; X : not assessed

Post-PECT : Favorable LPPR opinion

Post-PECT : Unfavorable LPPR opinion

Figure 2. Unfavorable PECT HTA opinions: Frequency of ineligibility criteria



Conclusion

- PECT facilitates early access to promising MDs but lacks alignment with procedure code creation and standard reimbursement pathways.
- Extended PECT listing delays and coverage durations show the need for stronger integration and clearer exit strategies to ensure clinical and economic sustainability.

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