CAHIR MEDTECH · EXECUTIVE BRIEF

Reimbursement & Coding Roadmap: executive brief

How MedTech teams plan coding, Medicare coverage and payment alongside the FDA decision, and how the Cahir MedTech Reimbursement & Coding Roadmap tracks each step.

Edition: November 2, 2026 · Go-to-market toolkit



Why it matters

FDA decides whether a device can be marketed. Payers decide whether to cover and pay for its use. Medicare covers items that are reasonable and necessary under Social Security Act §1862(a)(1)(A), a separate test from FDA review.

Coding, coverage and payment each run on their own calendars, so they need to be planned before the FDA decision, not after it.

The twelve roadmap steps

Step	What to decide or prepare	Where it is set
Existing code assessment	Whether current CPT, HCPCS or ICD-10-PCS codes fit; gaps documented.	AMA CPT / CMS HCPCS
CPT application	Category I or III application timed to the Editorial Panel calendar, if a new code is needed.	AMA CPT Editorial Panel
HCPCS Level II application	Application timed to the current CMS cycle, where applicable.	CMS HCPCS
Medicare coverage route	Existing policy, LCD request, NCD request or TCET.	CMS coverage process
TCET eligibility	Breakthrough designation status and nomination timing.	CMS TCET notice
Inpatient payment	MS-DRG assignment; NTAP application for the IPPS cycle.	CMS IPPS
Outpatient payment	APC assignment; transitional pass-through application.	CMS OPPS
Physician payment	Physician work and practice expense valuation path.	CMS PFS / RUC

Step	What to decide or prepare	Where it is set
Commercial payers	Top payer policies reviewed; evidence gaps logged.	Payer medical policies
Evidence gap plan	Coverage evidence linked to studies and registries.	Dual-intent evidence plan
Coding guidance	Customer billing guide reviewed by qualified coding counsel.	Internal review
Integrated timeline	Coding, coverage and payment milestones aligned with the FDA decision date.	Timeline sheet

What the workbook adds

- **Coverage routes:** Medicare coverage can come from National Coverage Determinations, Local Coverage Determinations issued by Medicare Administrative Contractors, or claim-by-claim review where no policy exists. TCET is a voluntary pathway for certain FDA-designated Breakthrough devices, and CMS accepts a limited number each year.
- **New-technology payment:** NTAP can add inpatient payment for qualifying technologies through the annual IPPS rulemaking cycle. Transitional pass-through payment can apply to qualifying outpatient devices, and CMS reviews applications quarterly.
- **Payer tracker and timeline:** track each payer's current position and next contact, and line up every milestone with the FDA decision. Confirm all dates on official CMS and AMA schedules.

Official sources

- AMA CPT Editorial Panel
- CMS HCPCS
- CMS TCET final notice
- CMS NTAP
- CMS OPPS pass-through

Workbook + guide · $299 USD one-time · Applicable taxes may apply. Companion guide: https://medtech.cahir.ai/go-to-market-guide · Toolkit dashboard: https://medtech.cahir.ai/workspace

Planning aid, not legal, coding or reimbursement advice. Confirm current cycles and requirements on official CMS, AMA and FDA pages.