Coverage and payment implications for breakthrough medical devices following Transitional Coverage of Emerging Technologies (TCET)

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Background

Recently, CMS issued a procedural notice outlining a Medicare coverage pathway to achieve a timely and predictable access for new medical technologies called TCET. The aim of TCET is the provide manufactures with breakthrough medical device designation a clear, transparent, and consistent coverage process for the Medicare population in the US. TCET outlines a pathway that allows manufacturers to engage early with FDA and CMS, that provides guidance on an evidence generation strategy to meet CMS' criteria for expedited coverage. CMS will work with manufacturers to ensure that evidence development under TCET does not require duplicative or conflicting evidence development with any FDA post-marketing requirements.

In addition to TCET, there are other pathways available to device manufacturers that may be considered in parallel to or instead of TCET. The objectives of this study were to: 1) Describe the TCET pathway in the US and considerations for devices granted Breakthrough Device Designation (BDD) and 2) Provide considerations for prioritizing pathways other than TCET.

Methods

CMS 2023 procedural notice, guidance documents, and public comments on the proposed TCET pathway were analyzed. Final rules published from 2013-2023 on all Medicare device payment and coverage pathways were identified via CMS, MedPAC, and the Federal Register sources.[2-6] Finally, eligibility criteria, expected timelines, pros, cons, risks and opportunities across each of the pathways were assessed as possible alternatives once TCET is implemented.

Results

The TCET pathway is divided into three distinct stages including 1) pre-market authorization, 2) pathway determination, and 3) post-launch coverage options. Once the FDA approves a device, the manufacturer submits an evidence preview and evidence development plan (EDP) with CMS-approved "fit for purpose" study designs. CMS then initiates a NCD process with a goal of completing it within six months. The TCET NCD is active for the necessary duration of evidence collection, which CMS estimates will take 3-5 years, compared to a standard NCD that can take more than 10 years. In addition to the TCET pathway, we found three coverage (NCD, NCD-CED, LCD) and two (NTAP and TPT) payment pathways as possible alternatives to TCET. Timelines, eligibility criteria, pros and cons, and risk profiles varied across pathways as shown in the table below.

Translational Coverage for Emerging Technologies Voluntary Pathway

Pre-market Authorization → *TCET may commence as early as **1 year** before FDA market authorization* → **TCET Pathway Determination** → NCD to be assigned within **6 months** of market authorization → **Post-launch Coverage Options**

Manufacturers will need to complete the following documents for CMS coverage review:

- CMS Evidence Review guidance
- Coverage with Evidence Development guidance
- Clinical Endpoints guidance
- Fit-For-Purpose study guidance

Manufacturers and CMS will participate in evidence review discussions to establish benefit category and coding requirements:

- Initiate benefit category and coding reviews before FDA authorization
- Evidence preview that summarizes the evidence
- CMS, FDA, AHRQ, and manufacturer meeting(s) to review evidence preview

CMS will determine coverage status based on the manufactures ability to meet the evidentiary criteria:

Sufficient evidence → **Expedited NCD**

Evidence gaps → **CED-NCD**

Manufacturers will be required to complete the **Evidence Development Plan** and participate in **periodic study progress updates** for safety surveillance.

Devices that receive an NCD will have permanent national Medicare coverage

The process for Medicare coverage under TCET pathway would follow the NCD statutory timeframes.[3]

Devices that receive CED-NCD must submit timely evidence for coverage reconsiderations

Possible Outcomes:
1) An NCD with continued CED requirements; 2) A "non-coverage" NCD; 3) Or rejection of coverage, transferring coverage to a regional MAC

Alternative Emerging Medical Device Payment and Coverage Pathways and Considerations for Device Manufactures in the Medicare Population /

		Background	Eligibility	Timelines	Pros	Cons	Risks
Coverage	Translational Coverage for Emerging Technologies [1]	**New potential expedited coverage** pathway provided by CMS	Medical devices with breakthrough designation (no prior NCD)	Takes between **1-2 years** for coverage determination	Provides a potentially **expedited coverage pathway for breakthrough devices**	Requires an extensive pre- or post-launch evidence package for NCD	Short term risk: CED designation would lead to limited coverage
	Coverage with Evidence Development [2]	Coverage determination provided by CMS **only in the context of ongoing clinical research or with additional data**	Medical devices with evidence that CMS deems insufficient for full coverage and **requests additional confirmatory data**	Varies; typically, **5-7** years	Devices that may not meet the NCD coverage evidence threshold, **may still obtain coverage**	Can be a **lengthy process** with complex requirements, data collection periods are unpredictable/extensive and often lengthy (8 years on average)	Following re-evaluation, coverage may be delegated to local Medicare Administrative Contractors (MACs) and **may lead to coverage variability**
	National Coverage Determination [3]	Coverage determination provided by CMS that **grants, limits, or excludes Medicare coverage nationally**	Medical devices that meet CMS' evidentiary and **'reasonable and necessary'** threshold for coverage	Can take **10 years or more** to establish sufficient level of evidence for positive coverage determination	Provides **consistent coverage** nationally	Generating the level of evidence for a positive NCD **can take a significant amount of time** and **negative NCDs may be extremely difficult to rescind**	CMS may deem the evidence to be insufficient and therefore may issue a **negative NCD**
	Local Coverage Determination [4]	Coverage determination developed by **Medicare Administrative Contractors** (MACs) at the **local level** that grants, limits, or excludes Medicare coverage	Medical devices that meet the 'reasonable and necessary' threshold for coverage **according to local MACs**	Varies; typically, **months to years**	Allows for **regional coverage** even if the device is not covered nationally	May result in **inconsistent, limited, or no coverage**	LCDs **may result in no coverage,** potentially resulting from a scenario where the MAC was implicitly covering the device/procedure but is no longer doing so following new coverage determination
Payment	New Technology-Add on Payment [5]	Payment mechanism used by CMS to provide **additional reimbursement** for certain qualifying new and innovative medical technologies/procedures	Applies to new (and/or technologies that demonstrate substantial clinical improvement compares to existing therapies) and costly technologies only in the inpatient setting	**1 year** between application deadline and effective payment status	Provides **additional payment** for eligible technologies	**Does not cover the full price** of the device	Uncertainty regarding **long-term payment following DRG re-engineering**
	Translational Passthrough Payment [6]	Available for **new technologies** with **evidence of clinical improvement compared to SOC**, and cost not insignificant relative to total procedure cost	Applies to **FDA approved devices in the outpatient setting** that meet the newness criterion (FDA approval or clearance is within 3 years of application date)	Earliest effective date for payment is **5 months following TPP application**	Facilitates **access to new and innovative devices/drugs** (in the outpatient setting) to drive utilization for these treatments that tend to be higher-cost	May **not fully support the price** of a device	Uncertainty regarding **long-term reimbursement**

Conclusion

If finalized, TCET will provide an additional pathway for securing separate payment for devices that can demonstrate substantial clinical improvement over the current standard of care. These pathways vary in terms of eligibility criteria, payment levels, and coverage timelines. As such, manufactures will need to conduct a benefit-risk assessment of choosing between TCET and other alternative pathways depending on the available evidence and long-term market access goals.

REFERENCES: 1: TCET bill, Federal Register :: Medicare Program; Transitional Coverage for Emerging Technologies, 2: Coverage with Evidence Development, Medicare Coverage Document - Guidance for the Public, Industry, and CMS Staff: Coverage with Evidence Development, 3: National Coverage Determination, Medicare Coverage Determination Process | CMS, 4: Local Coverage Determination, CMS, 5: New Technology-Add on Payment, Hospital Acute Inpatient Services Payment System (medpac.gov), 6 Translational Passthrough Payment, 42 CFR § 419.66 - Transitional pass-through payments: Medical devices. | Electronic Code of Federal Regulations (e-CFR) | US Law | LII / Legal Information Institute (cornell.edu)

Abbreviations: CMS: Centers for Medicare & Medicaid Services; TCET: Transitional Coverage of Emerging Technologies; BDD: Break-through Designation; NCD: National Coverage Determination; MAC: Medicare Administrative Contractor

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