

January 10, 2025

Medtronic (MDT): Renal Denervation Coverage Read-Through?

This morning's opening of a Medicare National Coverage Determination (NCD) for privately-held **Impulse Dynamics'** Optimizer System bolsters our view that coverage for renal denervation (RDN) systems [**Medtronic (MDT), Otsuka / ReCor (4578.JT)**] is unlikely to be established prior to YE25 or 1H26, even if a related coverage review is opened in the near-term.

What does the one have to do with the other? We're so glad you asked....

From a product standpoint, the answer is nothing, but we suspect there is read-through in terms of *process*, which in turn informs *timing*.

As CMS notes in the [Tracking Sheet](#) for today's NCD, "this is a Transitional Coverage for Emerging Technologies (TCET) **pilot** that tested the processes and concepts of TCET" (our emphasis), which investors will recall is a newly devised [program](#) established by CMS last year seeking to expedite coverage decisions for select breakthrough devices following FDA approval. The agency has signaled its goal of pursuing five TCET reviews each year, and there has been speculation that this may be a viable pathway for RDN.

Today's NCD opening is also the third such TCET "pilot" CMS has announced, with the first two having been for **Edwards Lifesciences' (EW)** Evoque Transcatheter Tricuspid Valve Replacement (TTVR) [[opened June 20, 2024](#)] and the second for **Abbott's (ABT)** TriClip Transcatheter Tricuspid Edge-to-Edge Repair (T-TEER) [[opened Oct. 3, 2024](#)].

First, The Good News

With EW's Evoque and ABT's TriClip having originally been participants in the joint CMS / FDA [Parallel Review](#) program – a kind of TCET predecessor – and both related to tricuspid valve services, our working assumption has been that these may be the only "pilot" test cases the agency employs. This assumption was bolstered by CMS's TCET [guidance](#), finalized in August 2024, stating that "nominations for devices that are already FDA market authorized or those anticipated to receive an FDA decision within six months of nomination will not be accepted."

FDA approved applicants, particularly those that were not previously in the Parallel Review pathway, may therefore have to navigate the *traditional* coverage process in which there is a standing [wait list](#) of eight other requests that CMS has already accepted but lacks the staffing capacity to initiate. Not only does RDN not appear on that list, but each review takes ~9 months to complete, and with a historic cadence of 4-5 NCDs per year, this could take some time.

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Medtronic PLC (MDT)

Price:	\$80.98
52-Week High:	\$92.68
52-Week Low:	\$75.96

The opening of today’s Impulse Dynamics NCD, however, suggests that not only is CMS looking out beyond the tricuspid space to employ fresh TCET pilots, but since – to our knowledge – neither they nor MDT / ReCor were Parallel Review participants, this approach remains a viable option for RDN to jump the wait list queue. In fact, Optimizer was first [approved](#) by FDA in March 2019, with its NCD request initially [submitted](#) in May 2022. This compares to the [Nov. 7, 2023](#) approval for ReCor’s RDN and [Nov. 17, 2023](#) for MDT’s Symlicity.

Now, The Bad News

- **In short, even if such a review were announced *today*, it is unlikely that coverage would be finalized and established before 4Q25.**

Each of the three announced TCET pilots are listed as having a full 9-month review schedule, consistent with traditional NCDs. This has triggered complaints from stakeholders, but we see little reason to suspect that RDN would merit an alternative approach.

TCET PILOTS	FDA APPROVAL	REQUEST	NCA OPEN	CMS PROJECTION	
				DRAFT NCD	FINAL NCD
Impulse Dynamics Optimizer	Mar 21, 2019	May 12, 2022	Jan 10, 2025	Jul 10, 2025	Oct 8, 2025
Months From Prior Step	--	38	32	6	3
ABT TriClip	Apr 1, 2024	Mar 17, 2023	Oct 3, 2024	Apr 3, 2025	Jul 2, 2025
Months From Prior Step	--	-13	19	6	3
EW Evoque	Feb 1, 2024	Feb 20, 2024	Jun 20, 2024	Dec 19, 2024	Mar 19, 2025
Months From Prior Step	--	1	4	6	3
Geomean		--	13	6	3
Average	--	9	18	6	3
Median		13	19	6	3

Source: CMS Coverage Database, Capitol Policy Partners

Separately, thus far the cadence between TCT pilot announcements has been ~3.5 months, which would imply an RDN coverage review being announced in late April. Given the historic consistency of NCD reviews, such a timeframe would suggest a draft policy being released in late October and the finalized version published by late January.

TIME BETWEEN TCET NCD OPENINGS	OPENED	DAYS Δ PRIOR TCET
Impulse Dynamics Optimizer	Jan 10, 2025	99
ABT TriClip	Oct 3, 2024	105
EW Evoque	Jun 20, 2024	--
Average	--	105
Implied RDN NCA Opened	Apr 25, 2025	
Implied Draft NCD	Oct 23, 2025	105
Implied Final NCD	Jan 21, 2026	

Source: CMS Coverage Database, Capitol Policy Partners

In other words, as we said, today’s announcement bolsters our view that Medicare coverage of RDN is unlikely to be established before YE25 or 1H26.

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