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Medtronic: Medicare RDN Coverage in 4Q24

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Medtronic PLC (MDT)

Price:	$81.79
52-Week High:	$92.68
52-Week Low:	$75.96

In keeping with expectations laid out in our note late last week, CMS's opening of a National Coverage Analysis (NCA) for renal denervation (RDN) [**Medtronic (MDT)**, **Otsuka (4578.JT) / ReCor**] this afternoon has a target completion date of **Oct. 11, 2024**. This implies that, following the start of a three-year transitional pass-through (TPT) payment for facilities Jan. 1, 2025, the companies would have 2.2 years of TPT benefits remaining once coverage is established. We should also note that, historically, the implementation of clear coverage standards has translated into a key inflection point for novel device volumes, with Medicare contractors hesitant to approve claims in the interim.

RDN COVERAGE TIMELINE	DATE	DAYS	MONTHS
FDA Approval	*Nov 7, 2023*	--	--
Coverage Request Submitted	*Dec 12, 2024*	*401*	*13.2*
RDN TPT Payment Start	***Jan 1, 2025***	***421***	***13.8***
Request Accepted / Initiated	**Jan 13, 2025**	32	1.1
Public Comments End	Feb 12, 2025	30	1.0
Draft NCD Issued	**Jul 13, 2025**	**151**	**5.0**
Public Comments End	Aug 12, 2025	30	1.0
Final NCD Issued	**Oct 11, 2025**	**60**	**2.0**
RDN TPT Payment End	***Dec 31, 2027***	***811***	***26.7***

Source: CMS, Capitol Policy Partners

MARGIN ESTIMATE	RECOR PARADISE	MDT SYMPLICITY
CY25 Base Rate	**$5,702**	**$5,702**
CPT Code	0339T	0339T
APC Group	5192	5192
Base Case Costs	**$7,197**	**$7,197**
Device	$2,330	$2,330
Service	$4,866	$4,866
Base Margin ($)	**-$1,495**	**-$1,495**
Base Margin (%)	**-21%**	**-21%**
TPT Amount	**$20,670**	**$13,670**
TPT Product	$23,000	$16,000
Device Offset	-$2,330	-$2,330
TPT Case Cost	**$27,866**	**$20,866**
Device	$23,000	$16,000
Service	$4,866	$4,866
TPT Case Total Payment	**$26,371**	**$19,371**
Margin ($)	**-$1,495**	**-$1,495**
Margin (%)	**-5.4%**	**-7.2%**

Source: CMS, Capitol Policy Partners

While the cumulative nine-month duration of the review is consistent with our expectations, as is the agency's characterization of the NCA as a "pilot" analysis under the new Transitional Coverage for Emerging Technologies (TCET) pathway established by CMS last year, it does come on the earlier end of our 1Q25-2Q25 range.

Prior to today's announcement, there had been just three other TCET "pilots" established, with the average time between each review opening being ~3.5 months. Given that the agency had just announced the last TCET pilot on Jan. 10, this had implied a review being initiated sometime between now and late April. Today's opening brings that average down to 2.3 months, and with CMS having previously targeted the initiation of five TCET reviews each year, there might yet be one more to come.

TIME BETWEEN TCET NCA OPENINGS	OPENED	MONTHS Δ PRIOR TCET
MDT Symplicity / ReCor Paradise	Jan 13, 2025	0.1
Impulse Dynamics Optimizer	Jan 10, 2025	3.3
ABT TriClip	Oct 3, 2024	3.5
EW Evoque	Jun 20, 2024	--
Average	**--**	**2.3**

Source: CMS, Capitol Policy Partners

The use of TCET implies that – as MDT has acknowledged – this will likely be a Coverage with Evidence Development (CED) policy that requires facilities, operators, and patients to participate in a registry / study designed to address what is viewed as key evidentiary gaps. Historically, this has seen initial volumes stem from larger / integrated medical systems that possess the infrastructure needed to comply with CED strictures.

With respect to what evidentiary gaps the study itself may be designed to address, CMS notes only the following:

"This NCA will analyze clinical evidence for characteristics or comorbidities that make patients more or less likely to benefit from RDN and whether specific treatment conditions are necessary to achieve the outcomes demonstrated in clinical studies. Outcomes of interest may include office blood pressure, ambulatory blood pressure, nephroprotection, stroke, heart failure, decreased mortality, decreased emergency room or hospital admissions, and quality of life. The scope of this NCA is limited to radiofrequency and ultrasound based renal denervation procedures."

To date, we have seen just a single draft NCD issued for the three prior TCET pilots [*see here*], where we would view the associated criteria as fairly benign for facilities. Atypically, however, the proposal would require the associated CED study to include an active comparator. In the context of RDN, this would imply a sham-implant control group. While we view this as unlikely, we *do* think that CMS will maintain its focus on CED generating meaningful clinical insights that can inform real-world utilization decisions.

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