November 4, 2024

[MDT, BSX, LIVN, CVRX] Medtech Medicare Rule Puts & Takes

John Leppard
202-935-0238
john.leppard@capitolpolicypartners.com

Key Takeaways: We appear to have run the table with our pre-rule expectations [*here*, *here*] following CMS's release Friday of its CY25 hospital outpatient payment rule, which includes the following company-specific implications:

- **MDT & Otsuka / ReCor [Modest Positive]:** The agency's finalization of transitional pass-through payments (TPT) for renal denervation (RDN) was likely anticipated. While nevertheless positive, the benefits may also be constrained by: (A) our ongoing belief that it will likely be 1-2 years before broad Medicare *coverage* is in place, taking up much of the 3 year TPT period; and (B) CMS's rejection of MDT's request for combined TPT coding with Otsuka / ReCor, which would have provided more room for MDT price increases and / or facility margins.

- **CVRX [Positive]:** Agency reversal of its initial proposal to assign the Barostim heart failure system to a $30K payment group, deciding instead to maintain the current $45K payment for another year, likely brings hospital margins into positive territory [+7%] for CY25, rather than the negative ~25% implied under the draft rule. We would also not be surprised if CMS extended this assignment in CY26 given the planned transition to a new and permanent procedure code at that time.

- **LIVN [Negative]:** CMS's rejection of calls to reassign the company's vagus nerve stimulation (VNS) epilepsy treatment to a $45K payment group rather than its longstanding ~$30K assignment is unsurprising, and implies negative ~30% margins for CY25. We are at this point skeptical that the agency will make such efforts in CY26 either, despite ongoing calls to restructure the broader neurostimulator Ambulatory Payment Classification (APC) groupings.

- **BSX [Positive]:** CMS's reversal of its initial rejection of the company's TPT application for its Agent Drug Coated Balloon (DCB) catheter represents a ~65% improvement in payments relative to the proposal. While this will make Agent more economically attractive to facilities, margins will likely remain negative until case times / workflows improve, but we would not be surprised to see reassignment to a higher-paying APC group in future rulemakings, bringing an additional 20%-35% in reimbursement.

Medtronic PLC (MDT)

Price:	$90.04
52-Week High:	$92.68
52-Week Low:	$69.32

Boston Scientific Corp (BSX)

Price:	$83.62
52-Week High:	$88.79
52-Week Low:	$50.84

LivaNova PLC (LIVN)

Price:	$51.13
52-Week High:	$64.48
52-Week Low:	$42.75

CVRx Inc (CVRX)

Price:	$13.40
52-Week High:	$33.14
52-Week Low:	$6.40

MDT & Otsuka / ReCor [Modest Positive]: Renal Denervation (RDN)

After voicing its apparent support for establishing TPT payments for MDT's Symplicity Spyral and Otsuka / ReCor's Paradise in its July proposal, CMS's finalization should provide improved facility margins for ***covered*** services, but the reimbursement decision itself does not impose any coverage requirements on either the agency or Medicare Administrative Contractors (MACs). This likely remains a necessary step for a meaningful inflection point in utilization, and we suspect the coverage process will take longer than many investors anticipate.

RENAL DENERVATION MARGIN ESTIMATES	CY25 PROPOSAL	CY25 FINAL	%Δ PROPOSAL
MDT Symplicity	**$20,770**	**$19,371**	**-7%**
Pass-Through Payment	$15,068	$13,670	-9%
Baseline Payment	$5,701	$5,702	0%
Total Costs	$20,124	$20,866	4%
Device Costs	*$16,000*	*$16,000*	0%
Service Costs	*$4,124*	*$4,866*	18%
Margin ($)	$646	-$1,495	--
Margin (%)	3%	-7%	--
Otsuka / ReCor Paradise	**$27,770**	**$26,371**	**-5%**
Pass-Through Payment	$22,068	$20,670	-6%
Baseline Payment	$5,701	$5,702	0%
Total Costs	$27,124	$27,866	3%
Device Costs	*$23,000*	*$23,000*	0%
Service Costs	*$4,124*	*$4,866*	18%
Margin ($)	$646	-$1,495	--
Margin (%)	2%	-5%	--

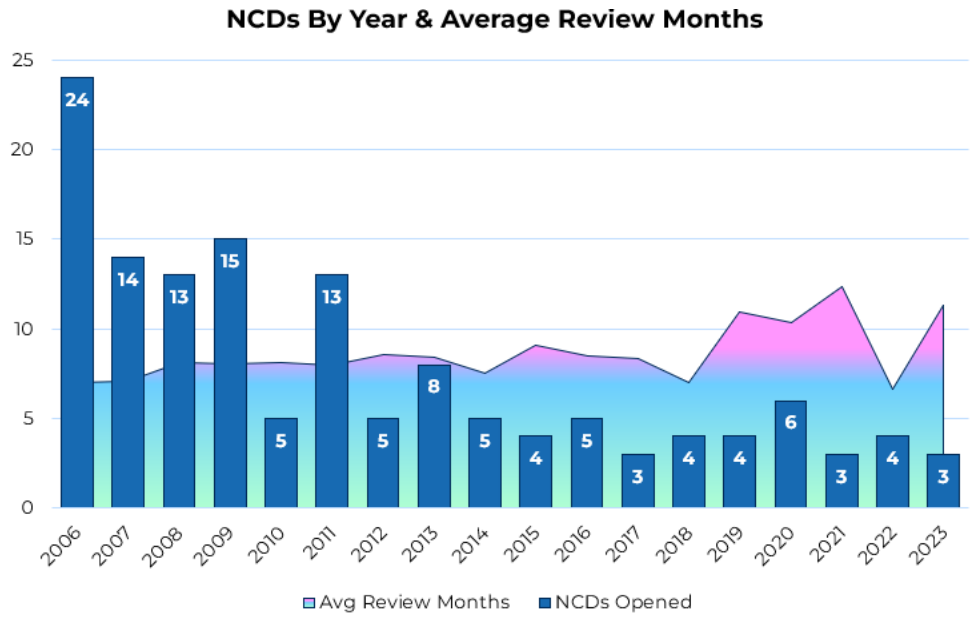
Source: CMS, Capitol Policy Partners

Regarding the TPT itself, however, one area where MDT fell short is its request that CMS establish a joint "device category code" to facilitate add-on payments for *both* radiofrequency (i.e., Symplicity) *and* ultrasound (i.e., Paradise) modalities, deciding instead to make a clear delineation between the two, as supported by Otsuka / ReCor.

In short, with Symplicity's $16K price point more than 30% less that Paradise's $23K, combination coding would have allowed hospitals to conflate the two products in their charge data and, as noted by Otsuka / ReCor, "lead to their undercharging for one technology and overcharging for the other." Such flexibility would have given MDT additional room for price increases and / or improved facility margins. Under CMS's final decision, however, both will likely need to operate within the established $16K baseline.

The more important element for RDN market penetration remains **coverage** and, despite expectations by some that this is likely to be established in the near-term, that belief likely needs to be tempered by ongoing capacity constraints at CMS.

As outlined in the agency's most recent National Coverage Determination (NCD) Wait List, which shows formally submitted and ***accepted*** coverage requests that the agency is unable to begin due to staff limitations, there is currently a backlog of nine NCDs that must be completed, some of which have been pending since 1H23. Importantly, each NCD takes 9-10 months to complete, and there are an additional four cover analyses that are already under review, which is roughly consistent with CMS's average over the last 10 years.



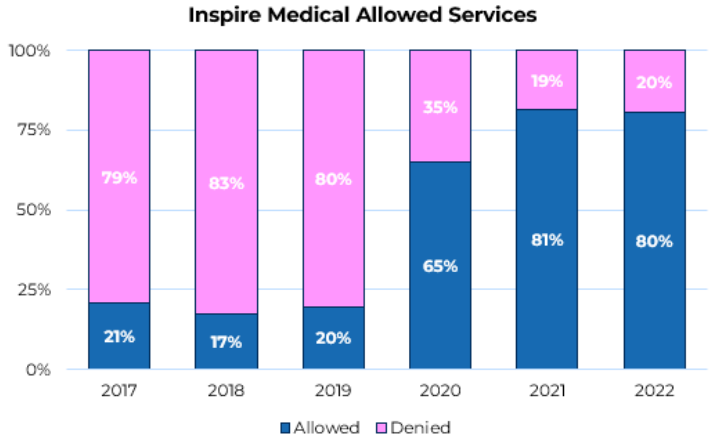
Source: CMS Medicare Coverage Database

To be clear, CMS is *not* obligated to proceed through this list in chronological order, and – per established guidelines – typically "prioritizes these requests based on the magnitude of the impact on the Medicare program and its beneficiaries." It is therefore possible that RDN's indication for the treatment of an estimated ~30M Medicare patients with uncontrolled hypertension will lead to its being expedited, but it should be noted that other currently waitlisted items also boast large patient populations (e.g., colorectal cancer screening, diabetes / insulin pumps).

We therefore think at least *some* of these pre-existing requests will be initiated before the agency turns its attention to RDN, where addressing even just those two topics would imply an RDN start date in mid-2025. This would initiate a 9-10 month process before a finalized coverage policy takes effect in ~2Q26.

The relevance is that, with TPT *reimbursement* limited to the three years from Jan. 1, 2025 to YE27, actual *coverage* of RDN services along such a timeline would mitigate ~50% of the pass-through benefit period.

This is notable in that, as with other novel technologies, there is a clear correlation between the establishment of defined coverage criteria and the aggregate percentage of services that actually receive payment. Using **Inspire Medical's (INSP)** hypoglossal nerve sleep apnea product as an example, which was approved by FDA in 2014 and received unique billing code procedures in 2017, it did not secure broad Medicare coverage until 2Q20, at which point we see a clear inflection point in allowed services. Prior to that point, roughly 80% of all claims were denied payment.



Source: CMS claims data, Capitol Policy Partners

CVRX [Positive] & LIVN [Negative]: Neurostimulator Payments

As noted in our pre-rule expectations, the Barostim System (CPT 0266T) had been assigned to a New Technology APC for CY24, which is typically reserved for either *new* products lacking cost / claims data, those with low volumes, or those undergoing a significant coding change (e.g., transition from temporary Cat III to permanent Cat I coding, loss of TPT). For CVRX, this grouping was based on its historically low volumes, high costs, and its TPT expiration at YE23.

Considering that such assignments typically last 2-3 years, allowing CMS to collect claims data that can be used for future grouping under a more traditional *clinical* APC, it unsurprising that CMS would extend this assignment for an additional year.

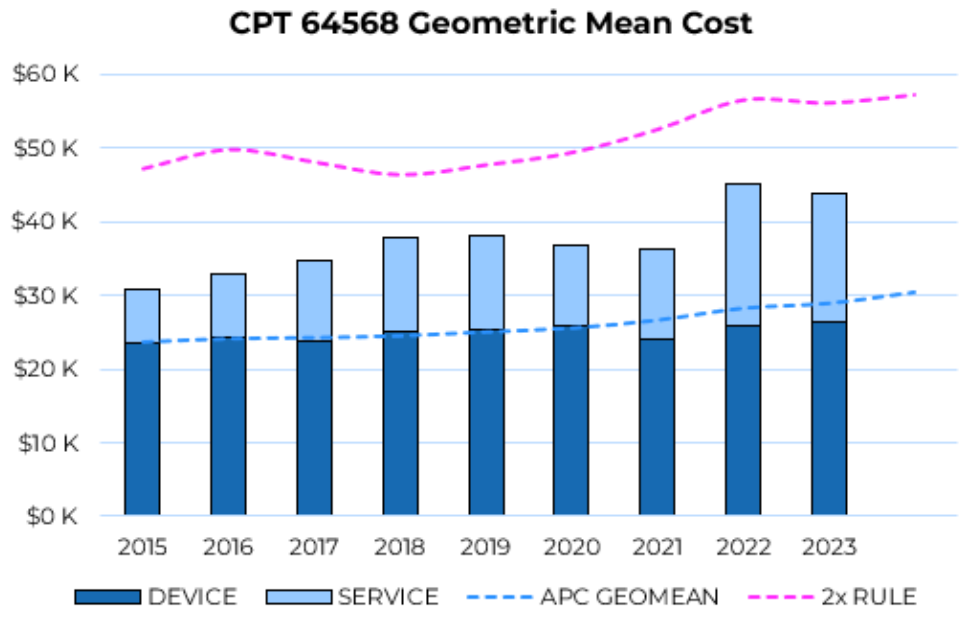
MARGIN ESTIMATES	CY24	CY25 PROPOSAL	CY25 FINAL	%Δ YOY	%Δ PROPOSAL
CVRX Barostim Payment	**$45,001**	**$30,198**	**$45,001**	**0%**	**49%**
Total Services	123	262	294	139%	12%
Case Costs	$45,502	$41,069	$41,934	-8%	2%
Device Costs	*$39,708*	*$25,722*	*$38,970*	--	--
Service Costs	*$5,794*	*$15,347*	*$2,964*	--	--
Margin ($)	-$502	-$10,872	$3,066	--	--
Margin (%)	-1%	-26%	7%	--	--
LIVN Vagus Payment	**$29,586**	**$30,198**	**$30,474**	**3%**	**1%**
Total Services	250	221	278	11%	26%
Case Costs	$45,175	$44,127	$43,800	-3%	-1%
Device Costs	*$25,764*	*$26,097*	*$26,433*	--	--
Service Costs	*$19,411*	*$18,030*	*$17,367*	--	--
Margin ($)	-$15,589	-$13,930	-$13,326	--	--
Margin (%)	-35%	-32%	-30%	--	--

Source: CMS, Capitol Policy Partners

Looking forward, however, investors will also be aware that CVRX recently received American Medical Association (AMA) endorsement of a transition from its current temporary Cat III code to permanent Cat I, with a Jan. 1, 2026 effective date. While this process *does* typically involve an erosion of **physician** payments – which we will first see in CMS's CY26 rulemakings next summer – the change will also allow CVRX to argue that its New Technology APC **facility** payments should be extended for a third year in CY26. This is in addition to improved *coverage* prospects, given that – definitionally – Cat I codes are designed for services that are "consistent with current medical practice" whose efficacy has been well validated in clinical literature.

Alternatively, the transition could prompt CMS to pursue the creation of a new neurostimulator payment group to which several other low volume / high cost procedures would be assigned, as industry has repeatedly requested and that we estimate would result in hospital payments of ~$43K, or ~40% above the current maximum of $30.4K. That said, the agency's final rule language on this possibility did not strike us as particularly supportive, writing that "we believe that the five level APC structure for the series continues to remain appropriate."

The case history of LIVN's vagus nerve stimulation (VNS) code CPT 64568 is largely the inverse of CVRX. While it *does* have similarly low volumes, it has nearly a decade of claims data at this point and has endured no meaningful coding / reimbursement changes, while also remaining well within CMS's "2x Rule" that defines the upper and lower cost thresholds for clinical APC assignments. We therefore suspect that it will remain in this $30K grouping unless / until the agency restructures the broader neurostimulator APC family.



Source: CMS, Capitol Policy Partners

BSX [Positive]: Agent DCB Catheter

CMS's reversal of its initial skepticism of BSX's TPT application will likely allow for a ~65% improvement in facility payments relative to the agency's initial proposal, but our cost estimates – which we should note are more generous than those put forward by BSX itself – also suggest that margins are likely to remain negative. Whereas we have assumed that typical Agent DCB cases imply ~$11.6K in hospital costs, the company puts this closer to $18.9K, albeit based on an evaluation of services at just a single facility.

BSX AGENT MARGIN ESTIMATES	CY25 PROPOSAL	CY25 FINAL	%Δ PROPOSAL	CY26-CY27 TPT + APC 513	%Δ CY25
BSX Agent Case Payments	**$5,702**	**$9,434**	**65%**	**$12,758**	**35%**
Pass-Through Payment	--	*$3,733*	--	*$1,417*	*-62%*
Baseline Payment	*$5,702*	*$5,702*	*0%*	*$11,341*	*99%*
Total Costs	$11,622	$11,622	0%	$11,622	0%
Device Costs	*$5,500*	*$5,500*	0%	*$5,500*	0%
Service Costs	*$6,122*	*$6,122*	0%	*$6,122*	0%
Margin ($)	**-$5,921**	**-$2,188**	**--**	**$1,135**	**--**
Margin (%)	**-51%**	**-19%**	**--**	**10%**	**--**

Source: CMS, Capitol Policy Partners

BSX COST ESTIMATES			
MINIMUM	MEDIAN	MAXIMUM	GEOMEAN
$13,125	$17,990	$28,297	$18,936

Source: BSX, CMS HOP Panel Presentation (Aug. 26, 2024)

That being said, we remind investors that procedure APC assignments are based on the "2x Rule," which states that no service within a given grouping can have geometric mean costs greater than 2x those of the lowest cost procedure within that same APC. Services exceeding this limit are reassigned to the next highest APC. For CY25, CMS has assigned the Agent DCB service code (0913T) to APC 5192, which has a payment rate of $5,702 and a 2x threshold of $9,761. The next level up would be APC 5193, which has a CY25 payment rate of $11,341 (+98%).

Using either our own cost estimate ($11,622) or those from BSX ($18,936) would exceed this upper limit by 19% and 94%, respectively, and even BSX's minimum estimate ($13,125) would breach this threshold by more than 30%. We therefore

suspect BSX will continue to advocate for APC reassignment in future rulemakings and – based on our analysis at least – they have a point.

DISCLOSURES AND DISCLAIMERS

Analyst Certification

The analyst, Capitol Policy Partners, primarily responsible for the preparation of this research report attests to the following: (1) that the views and opinions rendered in this research report reflect his or her personal views about the subject companies or issuers; and (2) that no part of the research analyst's compensation was, is, or will be directly related to the specific recommendations or views in this research report.

Analyst Certifications and Independence of Research.

Each of the Capitol Policy Partners analysts whose names appear on the front page of this report hereby certify that all the views expressed in this Report accurately reflect our personal views about any and all of the subject securities or issuers and that no part of our compensation was, is, or will be, directly or indirectly, related to the specific recommendations or views of in this Report. Capitol Policy Partners (the "Company") is an independent equity research provider. The Company is not a member of the FINRA or the SIPC and is not a registered broker dealer or investment adviser. Capitol Policy Partners has no other regulated or unregulated business activities which conflict with its provision of independent research.

Limitation Of Research And Information.

This Report has been prepared for distribution to only qualified institutional or professional clients of Capitol Policy Partners. The contents of this Report represent the views, opinions, and analyses of its authors. The information contained herein does not constitute financial, legal, tax or any other advice. All third-party data presented herein were obtained from publicly available sources which are believed to be reliable; however, the Company makes no warranty, express or implied, concerning the accuracy or completeness of such information. In no event shall the Company be responsible or liable for the correctness of, or update to, any such material or for any damage or lost opportunities resulting from use of this data. Nothing contained in this Report or any distribution by the Company should be construed as any offer to sell, or any solicitation of an offer to buy, any security or investment. Any research or other material received should not be construed as individualized investment advice. Investment decisions should be made as part of an overall portfolio strategy and you should consult with a professional financial advisor, legal and tax advisor prior to making any investment decision. Capitol Policy Partners shall not be liable for any direct or indirect, incidental or consequential loss or damage (including loss of profits, revenue or goodwill) arising from any investment decisions based on information or research obtained from Capitol Policy Partners.

Reproduction And Distribution Strictly Prohibited.

No user of this Report may reproduce, modify, copy, distribute, sell, resell, transmit, transfer, license, assign or publish the Report itself or any information contained therein. Notwithstanding the foregoing, clients with access to working models are permitted to alter or modify the information contained therein, provided that it is solely for such client's own use. This Report is not intended to be available or distributed for any purpose that would be deemed unlawful or otherwise prohibited by any local, state, national or international laws or regulations or would otherwise subject the Company to registration or regulation of any kind within such jurisdiction.

Copyrights, Trademarks, Intellectual Property.

Capitol Policy Partners, and any logos or marks included in this Report are proprietary materials. The use of such terms and logos and marks without the express written consent of Capitol Policy Partners is strictly prohibited. The copyright in the pages or in the screens of the Report, and in the information and material therein, is proprietary material owned by Capitol Policy Partners unless otherwise indicated. The unauthorized use of any material on this Report may violate numerous statutes, regulations and laws, including, but not limited to, copyright, trademark, trade secret or patent laws.