October 28, 2024

[BSX, MDT, LIVN, INSP, CVRX] Catalyst Watch: Medicare Rate Rule Prep Pack

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Key Takeaways: With CMS likely to release its final CY25 hospital outpatient payment rule by Friday (typically aftermarket) or early next week, we offer the following expectations for key product payment decisions, listed in market cap order:

- **BSX / MDT:** We think **pulsed field ablation (PFA)** [BSX's Farapulse, MDT's PulseSelect] is *unlikely* to receive a Transitional Pass-Through (TPT) payment, implying negative 15%-20% facility margins, with the same being true of newly approved integrated mapping catheters [BSX's Farawave, MDT's Affera / Sphere-9].
- **BSX:** We *do* expect a ~100%+ improvement in payments for the **Agent Drug Coated Balloon (DCB)** catheter relative to CMS's July proposal, leaving margins flat to slightly negative as volumes scale and workflow improves.
- **MDT / Otsuka:** We suspect CMS *will* finalize its TPT payment for **renal denervation (RDN)** services, providing positive hospital margins, but will stop short of MDT's request for combined coding to allow it to benefit from Otsuka's higher price point. That said, volume growth will likely be driven more by *coverage* policy, which we think will take longer than the market expects [review opened ~mid-2025].
- **LIVN:** We think CMS is *unlikely* to agree with advisory panel recommendations to increase **vagus nerve stimulation (VNS)** epilepsy service payments by 40%-50% relative to the July proposal, leaving negative ~30% facility margins in place another year. If we are incorrect, however, the change would likely have a negative read-through for **INSP's obstructive sleep apnea (OSA)** franchise.
- **CVRX:** Conversely, we *do* think the odds favor CMS endorsing the advisory panel's recommendation for a 40%-50% rate increase for the **Barostim heart failure system** relative to the proposal, leaving payments / margins roughly flat YoY.

Boston Scientific Corp (BSX)

Price:	$85.48
52-Week High:	$88.79
52-Week Low:	$49.56

Medtronic PLC (MDT)

Price:	$91.24
52-Week High:	$92.68
52-Week Low:	$68.84

Otsuka Holdings Co Ltd ADR (OTSKY)

Price:	$29.86
52-Week High:	$31.14
52-Week Low:	$16.28

LivaNova PLC (LIVN)

Price:	$53.68
52-Week High:	$64.48
52-Week Low:	$42.75

Inspire Medical Systems Inc (INSP)

Price:	$198.60
52-Week High:	$257.40
52-Week Low:	$123.00

CVRx Inc (CVRX)

Price:	$10.37
52-Week High:	$33.14
52-Week Low:	$6.40

BSX / MDT: Pulsed Field Ablation (PFA)

Unsurprisingly, and as noted in its Sept. 9 letter to CMS, "Medtronic **withdraws** the transitional pass-through payment application for the PulseSelect PFA System from consideration" in the CY25 rate rule [*our emphasis*]. With BSX not having submitted an application of its own for Farapulse – but rather looking to share any endorsement for MDT – it is unlikely that either company will see Medicare PFA bonus payments, including for recently approved mapping products.

This withdrawal stems from CMS's July assessment confirming our longstanding expectation that, as MDT now acknowledges, PulseSelect "does not meet the second and third cost significance requirements" for TPT, where ***all three*** must be met.

TPT COST CRITERIA
(1) TPT device costs **must be greater than 25%** of the payment rate for the associated service ✓
(2) TPT device costs **must be 125% of all devices** already included in the procedure's payment ✗
(3) The cost difference between TPT device and **all devices** already included in the procedure's payment **must exceed 10%** of the procedure's payment ✗

Source: 42 CFR §419.66

It is important to remember that CMS's assessment compares the costs of a TPT device applicant against the costs of ***all*** devices currently incorporated into the procedure's payment rate, rather than merely the device it is replacing (e.g., ablation or mapping catheters), with the full array ablation inputs listed below.

TRADITIONAL ABLATION DEVICE COMPONENTS	COST	% COST
Ablation Catheter	$3,986	33%
Echocardiography Catheter	$3,057	25%
Mapping Catheter	$2,018	17%
Steerable Sheath	$1,073	9%
Coronary Sinus Catheter	$571	5%
Patch	$479	4%
Transseptal Needle	$300	2%
Quads	$254	2%
Guiding Sheath	$231	2%
Irrigation Tubing	$115	1%
TOTAL	**$12,083**	**100%**

Source: CMS Cost Files, Innovative Health, Adjusted for CY25

Based on the $9,750 PulseSelect price point provided to CMS by MDT, the ~$24K payment rate for standard ablation procedures billed under CPT 93656, as well as the $12K in device costs already incorporated into the baseline Medicare payment, we can see that PFA component costs would likely need to be ~$15,200. While we have not seen explicit pricing information from BSX, we think it unlikely the company would charge hospitals 1.5x more than MDT, and anything below that figure would fail the TPT cost criteria, which BSX itself appears to acknowledge in its own letter to CMS.

	A	B	C		
TPT CRITERIA	**PFA CATHETER**	**PROCEDURE BASE PAYMENT**	**INCLUDED DEVICE COSTS**	**PFA COSTS NEEDED**	**%Δ COSTS REPORTED**
Data Inputs	**$9,750**	**$24,104**	**$12,083**	**$15,200**	**56%**
Criteria #1: (A ÷ B)		**40%**		**63%**	
Criteria #2 (A ÷ C)		**81%**		**126%**	
Criteria #3: (A - C) ÷ B		**-10%**		**13%**	

Source: CMS Cost Statistics, Capitol Policy Partners

With FDA having recently approved integrated PFA + navigation mapping catheters from both BSX (Farawave) and MDT (Affera / Sphere-9), we are similarly dubious that these devices would qualify for TPT should they apply, as their costs would still need to equal ~$15,200, and pricing at this level would represent a 2.5x premium over the current *combined* costs of typical ablation + mapping products.

With CMS's proposed $24K ablation procedure base rate therefore serving as our base case – along with traditional ablation costs per procedure of ~$27K per procedure, as outlined in agency data files – below we outline the facility margin implications for cases where BSX / MDT products replace existing ablation, mapping, and other catheters currently baked into CMS cost assumptions.

PFA MARGIN ESTIMATE	TOTAL AMOUNT	NO MAPPING	NO MAP / ECHO CATH	NO OTHER CATHETERS
CY25 Base Rate	**$24,104**	**$24,104**	**$24,104**	**$24,104**
Procedure Cost	**$33,138**	**$31,119**	**$28,063**	**$26,419**
Service	$15,291	$15,291	$15,291	$15,291
Device	$17,847	$15,828	$12,772	$11,128
PFA Catheter	*$9,750*	*$9,750*	*$9,750*	*$9,750*
Echo Catheter	*$3,057*	*$3,057*	×	×
Mapping Catheter	*$2,018*	×	×	×
Steerable Sheath	*$1,073*	*$1,073*	*$1,073*	×
Coronary Sinus Catheter	*$571*	*$571*	*$571*	×
Other "Device" Inputs	*$1,378*	*$1,378*	*$1,378*	$1,378
Margin ($)	**-$9,034**	**-$7,015**	**-$3,959**	**-$2,315**
Margin (%)	**-27%**	**-23%**	**-14%**	**-9%**

Source: CMS Cost Files, PulseSelect Pricing, Innovative Health, Capitol Policy Partners

BSX: Agent Drug Coated Balloon

We expect the final CY25 rule to improve upon CMS's July proposal by (A) reassigning the procedure itself into a higher-paying Ambulatory Payment Classification (APC) group; and/or (B) reversing its preliminary denial of the company's TPT application. Relative to this summer's draft, this would roughly double facility payments.

PROPOSAL vs TPT vs NEW APC	PROPOSAL	NEW APC	TPT	NEW APC + TPT
CY25 Payment	**$5,701**	**$11,293**	**$12,609**	**$12,787**
%Δ vs Proposal	--	**98%**	**121%**	**124%**
Procedure Cost	**$13,143**	**$13,124**	**$13,143**	**$13,124**
Device	$5,500	$5,500	$5,500	$5,500
Service	$7,643	$7,624	$7,643	$7,624
Margin ($)	**-$7,441**	**-$1,832**	**-$534**	**-$337**
Margin (%)	**-57%**	**-14%**	**-4%**	**-3%**

Source: CMS, Capitol Policy Partners

In addition to a formal recommendation for APC reassignment from CMS's Hospital Outpatient (HOP) Panel in August, Agent's $5.5K price point and volume-weighted service component costs of $7.6K associated with comparable percutaneous coronary interventions (PCI) implies that an upward revision is likely merited under longstanding ratesetting practices.

Recall that each procedure code in the hospital outpatient system is assigned to an APC grouping – along with 20-40 others – based on both clinical and cost similarities. The latter's thresholds are governed by CMS's "2x Rule" stating that no service within an APC can have a geometric mean cost (GMC) that is more than 2x that of the lowest cost service within that same group.

For the initial CY25 proposal, CMS had assigned Agent DCB procedure code 0913T to APC 5192, paying $5,701, with the APC's 2x Rule upper bound being $10,006. Assuming Agent device-related costs of $5.5K and service / operating costs of $7.6K would imply a cumulative GMC of ~$13.1K, or 30% above the threshold required for assignment to APC 5193, reimbursement for which is likely to be $11.3K for CY25.

We should note that assignment to a new APC does *not* preclude Agent procedures from *also* receiving TPT payments. Our review of the procedure codes within APC 5193 cited by BSX as being permissible "for use with Agent DCB" shows that the device would continue to meet all three TPT cost criteria, with the payment / margin implications outlined above.

Unfortunately, however, the question of whether or not Agent is ultimately eligible for TPT hinges on the more subjective question of whether or not its "device category" can be "appropriately described by any of the existing categories or by any category previously in effect." CMS previously suggested in the July proposal that Agent could potentially be described by decade-old device category code C2623 [*catheter, transluminal angioplasty, drug coated, non-laser*] because the product "is a non-laser, drug coated catheter used for transluminal angioplasty."

BSX rebuts this finding in its comment letter to CMS, arguing that C2623 is *not* appropriate "because Agent is not used to perform transluminal angioplasty….[but is] used post-angioplasty to effectively deliver drug to the lesion."

We find BSX's reasoning persuasive in this regard, but caution that it is ultimately a subjective call for CMS, and that it often prefers to leverage *existing* codes where possible rather than to establish new delineations.

MDT / Otsuka: Renal Denervation (RDN)

Consistent with its July proposal, we expect CMS to finalize TPT payments for renal denervation products from MDT [Symplicity] and Otsuka [Paradise]. However, we have long viewed the volume ramp as being more contingent on Medicare *coverage* policies that we think will take longer to play out than many might be anticipating. In our view, CMS is unlikely to start that process until well into 2025, with completion in 2026, despite recent MDT commentary that "constructive conversations" with the agency suggest this catalyst "doesn't seem like it's that far off."

RENAL DENERVATION MARGIN ESTIMATE	RECOR PARADISE	MDT SYMPLICITY
Total Payment	**$27,770**	**$20,770**
Base Rate	$5,701	$5,701
Pass-Through Payment	$22,068	$15,068
Device Cost	*$23,000*	*$16,000*
Device Offset	*($932)*	*($932)*
Total Cost	**$27,124**	**$20,124**
Device	$23,000	$16,000
Service	$4,124	$4,124
Margin ($)	**$646**	**$646**
Margin (%)	**2.4%**	**3.2%**

Source: CMS Cost Files, Capitol Policy Partners

Starting first with TPT, the outstanding question for CMS has been whether to facilitate these payments via a single device category code, as favored by MDT, or to provide for two distinct codes that distinguish between the Symplicity [radiofrequency] and Paradise [ultrasound] modalities, as argued by Otsuka.

With the cost of Paradise [$23K] being ~40% [$7K] more than Symplicity [$16K], the practical effect of a combined approach would be the potential conflation of hospital charge data between the two, making MDT eligible for greater TPT payments than might otherwise be the case.

As outlined by Otsuka in its comment letter to CMS, "if [hospitals] are establishing charges for one device category that captures two differently priced renal denervation systems, this could lead to hospitals undercharging for one technology and overcharging for the other. As such, having two device categories will more easily allow hospitals to set charges that more accurately reflect the cost of each technology."

We suspect CMS will follow this line of reasoning, as it echoes concerns the agency outlined in its July proposal, in addition to the ability of two separate codes to better track differing clinical efficacy data / outcomes between products. Given the

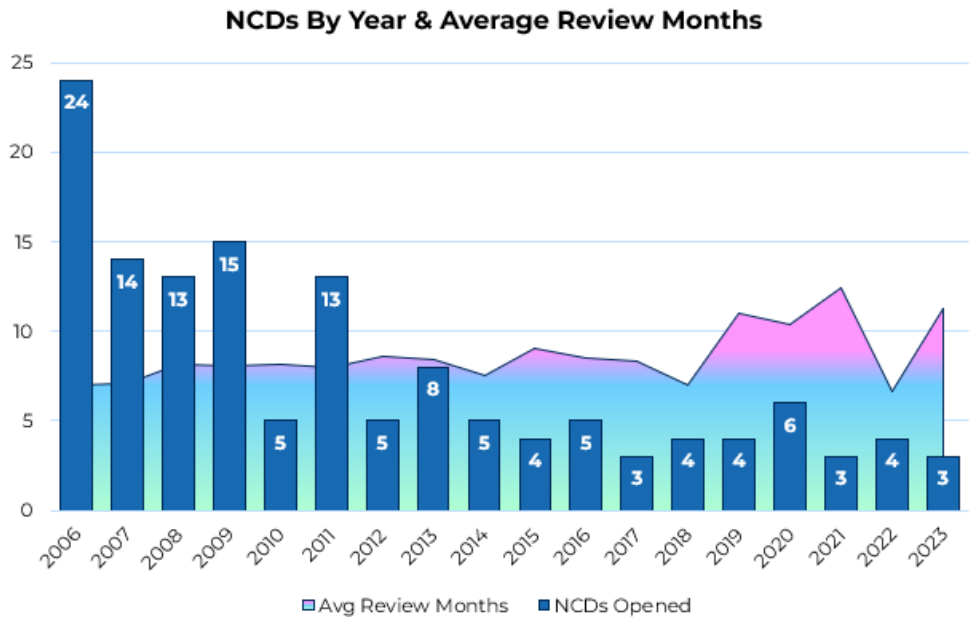
likelihood that any eventual Medicare National Coverage Determination (NCD) will rely on Coverage with Evidence Development (CED) – mandating the ongoing collection of device performance – this will likely be a relevant consideration for CMS.

Regarding the timing of that NCD, however, we believe investor expectations for the agency to initiate this 9-10 month process in the near-term should be tempered by ongoing capacity constraints at CMS. As outlined in its most recently published NCD Wait List of formal coverage requests that have already been accepted but that cannot yet begin due to staff limitations, there is a current **backlog of eight NCDs** that the agency must work through, some of which have been pending since summer 2023.

CMS is not obligated to proceed through its list in chronological order, and – per established guidelines – typically "prioritizes these requests based on the magnitude of the impact on the Medicare program and 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 other topics on the wait list *also* address large patient populations.

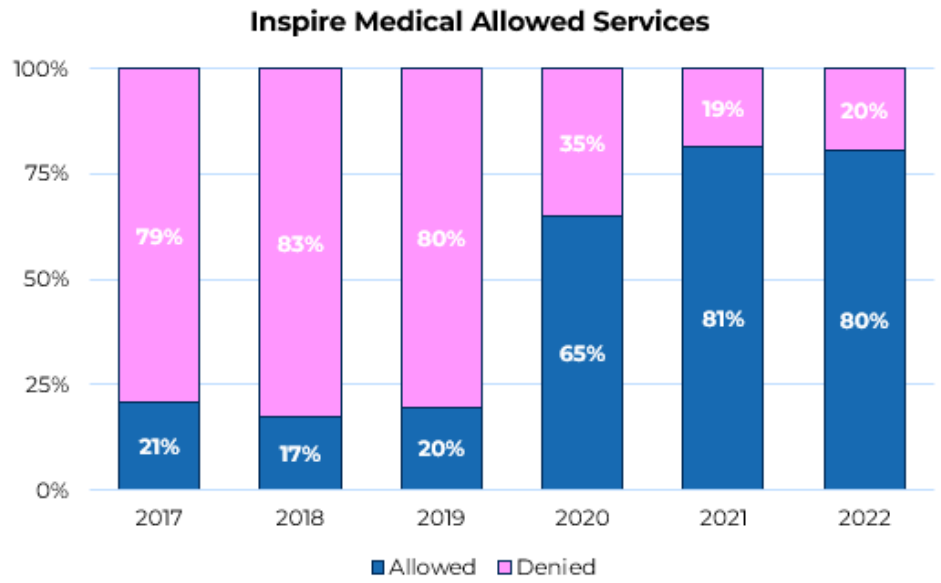
We therefore think at least *some* of these pre-existing requests will be initiated before RDN, where addressing only the two largest (e.g., colorectal cancer screening, diabetes / insulin pumps) would imply a start date in mid-2025 and completion in 1H26.

CMS currently has four coverage analyses under review, which is roughly consistent with historic norms [*see below chart*]. Of these, three are scheduled for completion by early June 2025, meaning that if CMS were to rapidly initiate the two largest outstanding NCDs following each review's conclusion, keeping the total "open" NCDs at four, the agency should have capacity to initiate an RDN analysis by late 2Q25.



Source: CMS, Capitol Policy Partners

The relevance of this timing for RDN volumes can be seen through the experience of **Inspire Medical's (INSP)** hypoglossal sleep apnea product. While clinically unrelated to RDN, this novel treatment of a widespread ailment long addressed via alternative methodologies was approved by the FDA in 2014, but did not secure broad Medicare coverage until 2Q20, at which point we see a clear inflection point in the ratio of allowed versus denied claims.



Source: CMS, Capitol Policy Partners

Amid clinical data weaknesses and a lack of clarity in the appropriate treatment population, we suspect the experience of RDN would be much the same in terms of covered claims by Medicare Administrative Contractors (MACs) until there is a formal coverage policy put into place.

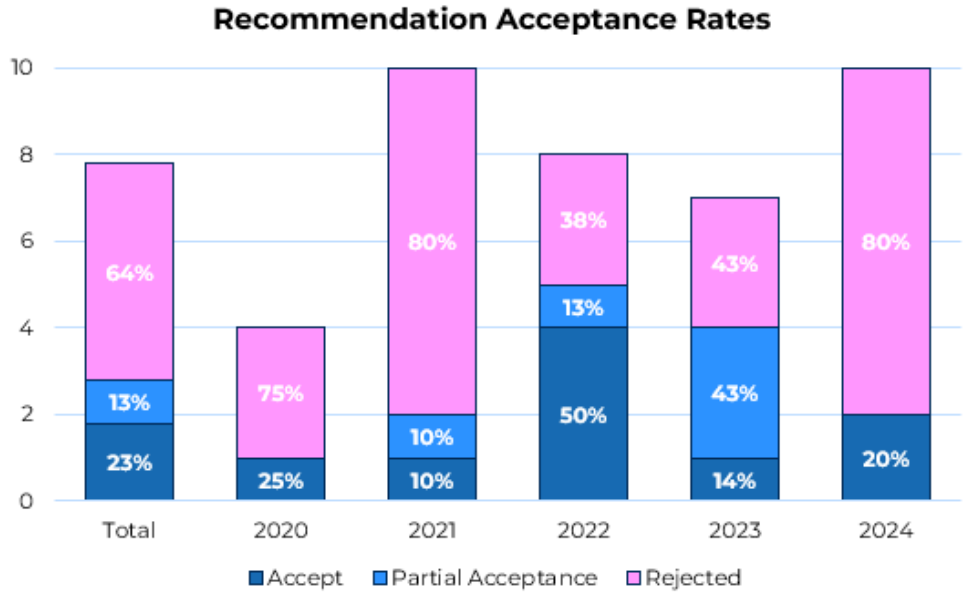
LIVN / CVRX: Neurostimulator Payment Groups

We think CMS is unlikely to adopt HOP Panel recommendations to create a *new*, higher paying APC group for neurostimulator services, which would increase payment rates for LIVN's VNS and CVRX's Barostim procedures from the draft rule's $30K to ~$42K (+40%). However, we *do* think it will allow CVRX's Barostim to remain in its current New Technology APC and its ~$45K payment rate for an additional year, in-line with the Panel's secondary recommendation, but that it is less likely to do so for LIVN, which we expect to remain in its current *clinical* APC group, with a $30K payment.

SCENARIO	CVRX	LIVN
Procedure Costs	**$41,069**	**$44,127**
Status Quo Payment (CY24)	**$45,001**	**$29,586**
Margin ($)	$3,931	-$14,541
Margin (%)	9%	-49%
CMS - CY25 Proposed Payment	**$30,198**	**$30,198**
Margin ($)	-$10,872	-$13,930
Margin (%)	-26%	-32%
%Δ YoY	-33%	2%
HOP Panel #1 - New Level 6 APC	**$41,560**	**$41,560**
Margin ($)	$491	-$2,567
Margin (%)	1%	-6%
%Δ YoY	-8%	40%
HOP Panel #2 - New Tech APC	**$45,001**	**$45,001**
Margin ($)	$3,931	$873
Margin (%)	10%	2%
%Δ YoY	0%	52%
OUR BASE CASE	**$45,001**	**$30,198**
Margin ($)	**$3,931**	**-$13,930**
Margin (%)	**10%**	**-32%**
%Δ YoY	**0%**	**2%**

Source: CMS, Capitol Policy Partners

To first put HOP Panel recommendations in context, CMS has historically rejected these more often than they have been accepted. Through the 2020-2024 rulemaking cycles, CMS has denied 25 of 39 (64%) recommendations and accepted just nine (23%). We classify the remaining five (13%) as partial acceptance, wherein CMS does not endorse the specific approach recommended by the panel, but nevertheless changes its initial recommendation in a way that is directionally consistent.



Source: CMS, Capitol Policy Partners

Furthermore, with the Panel's primary recommendation being the creation of an entirely *new* "Level 6 – Neurostimulator & Related Procedures" APC group to layer on top of the current five-level structure, payments for which we would estimate at ~$42K relative to the ~$30K for the current Level 5 group, we should note that such an approach was ***not*** listed as a possible outcome for CY25 in CMS's July proposal.

It would be highly atypical, in our view, for the agency to finalize a new APC level without having first outlined that possibility in draft form due to the distributional effects it would have on other groupings within the same APC family. In other words, with each APC payment based on the average costs associated with its component procedures, a restructuring would likely lead to a change in rates, and stakeholders must be afforded the opportunity to comment on such implications before it can be finalized.

Our bifurcated base case between LIVN and CVRX is therefore based on the potential for each to be assigned to a New Technology APC group for CY25, along with the coding and payment history of each procedure.

Recall that New Technology APCs are intrinsically designed to be temporary (1-3 years), paying for services based only on their reported costs while the agency collects claims data that would allow for permanent assignment to a *clinical* APC group. This can be particularly true of low-volume services – defined as < 100 claims in a given year – whereby outlier claims can meaningfully shift a procedure's average costs and lead to persistent APC reassignments due to 2x Rule violations, along with dramatic changes in reimbursement that disrupt access.

The goal of New Technology APCs is to smooth the transition period and minimize YoY disruptions stemming from a meaningful change in hospital billing practices or payment policy, such as implementation of a new billing code or expiration of TPT payments. The most salient consideration, however, is that New Technology APC exceptions are typically reserved for relatively ***new technologies*** – or at least new codes – that lack a history of claims data to facilitate permanent assignment to a clinical APC.

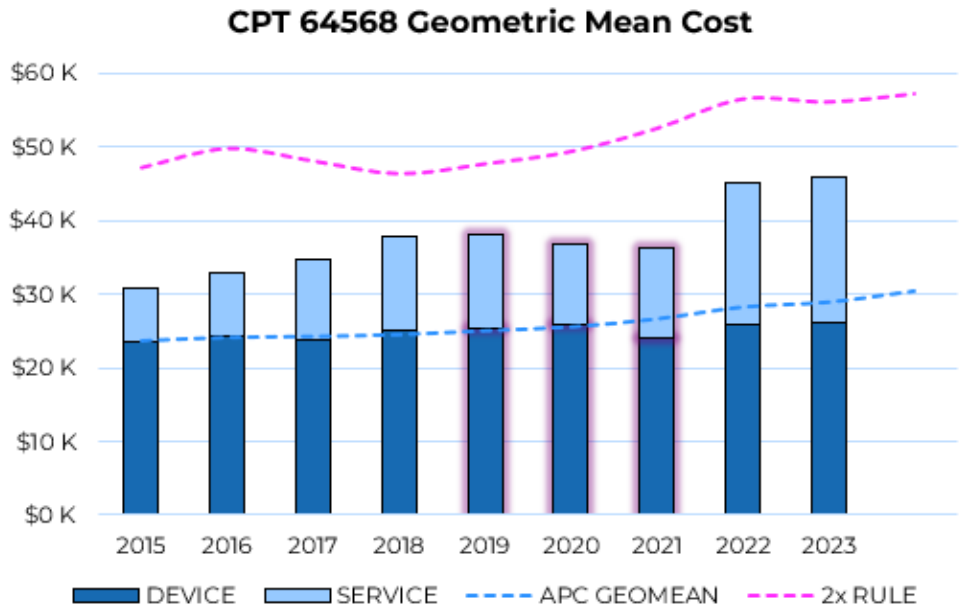
Investors will recall that CVRX's Barostim (CPT 0266T) had been paid under TPT status 2021-2023, at which point CMS initially proposed its permanent assignment to the Level 5 neurostimulator group in CY24 and its $29.6K payment. In light of the relatively low claims volume for that year [N = 96], significant YoY shifts in hospital reported costs, and the extent to which they exceeded the Level 5 group's payment rate, CMS was persuaded to temporarily assign the code to New Technology APC 1580 for CY24 to allow additional claims data to be collected. Given the typical 2-3 year duration of such assignments, it strikes us as reasonable for this to continue for an additional year in CY25.

CVRX BAROSTIM - CPT 0266T

PAYMENT YEAR	APC GROUP	TOTAL SERVICES	PAYMENT RATE	GEOMEAN CASE COST	%Δ GEOMEAN CASE COST
CY25-P	Level 5 Neurostim.	259	$30,198	$41,146	-10%
2024	New Tech. APC	96	$45,001	$45,502	488%
2023 (TPT)	Level 5 Neurostim.	63	$58,871	$7,743	-77%
2022 (TPT)	Level 5 Neurostim.	8	$42,423	$32,984	236%
2021 (TPT)	Level 5 Neurostim.	1	$36,254	$9,810	-61%
2020	Level 4 Neurostim.	0	$29,116	$25,041	--

Source: CMS Data Files, Capitol Policy Partners

In contrast, LIVN's VNS code (CPT 64568) has *not* endured any recent billing or payment policy shift and the procedure itself cannot be considered new, with claims data stretching back to 2014, culminating in 211 hospital outpatient services in the most recent claims year (i.e., > 100). Moreover, at no point in the last decade did the service's geometric mean costs trigger a 2x Rule violation, which includes the data on which CMS is relying for the CY25 rulemaking cycle.

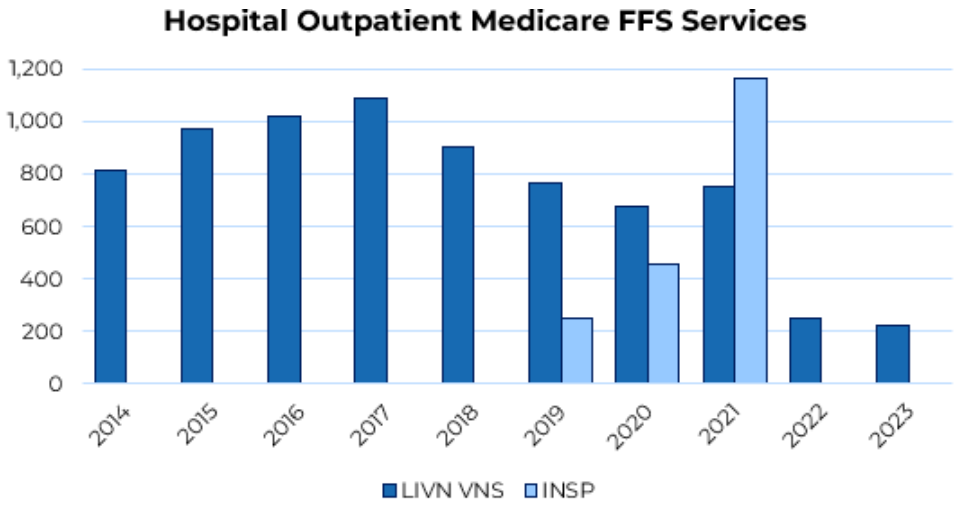


Source: CMS, Capitol Policy Partners

LIVN instead argues that – as investors will recall – VNS had previously served as the "base code" for INSP hypoglossal nerve procedures [*reflected in claims from the highlighted columns above*], with physicians billing CPT 64568 *plus* the 0466T hypoglossal add-on until such services were given their own unique billing code in CY22 [CPT 64582]. Accordingly, LIVN maintains that the VNS procedure's "true" costs have been hidden up to this point, and that the code should now be considered "new," making a New Technology APC assignment appropriate.

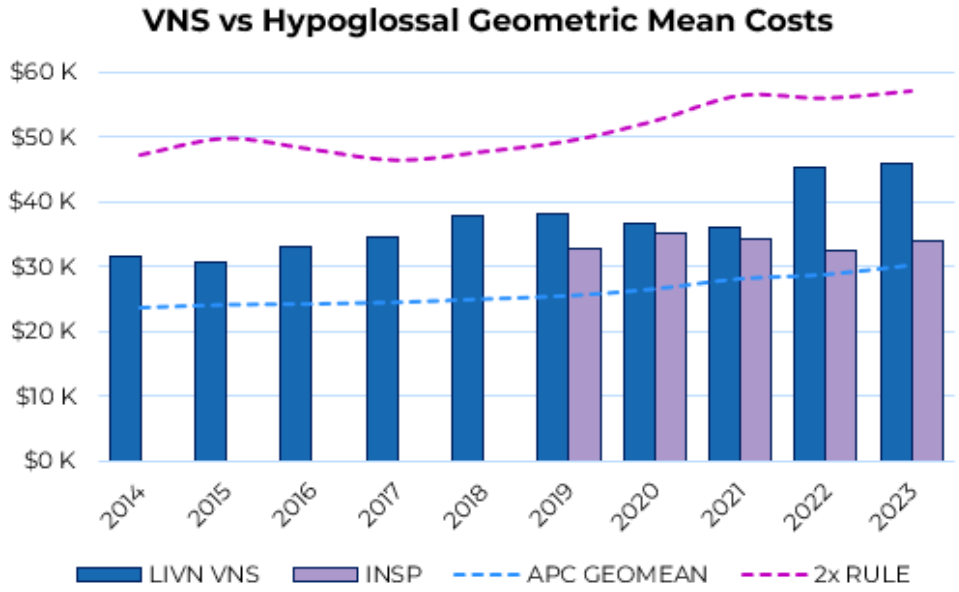
We think CMS will be unpersuaded by this line of reasoning for several reasons:

- First, literally *thousands* of billing codes are frequently used in conjunction with other services, but such "noise" in the claims data does not typically trigger cost-based New Technology APC payments, even amid meaningful volume changes. CMS instead just views this as the evolution of claims data and assigns these services through established processes (i.e., clinical APCs and 2x Rule thresholds).
- Second, while there claims data do show a clear and significant increase in service-related costs for CPT 64568 in CY22, following creation of INSP's unique hypoglossal code, this also coincides with a meaningful drop in VNS volumes, suggesting that the increase could be due more to the smaller denominator rather than the "true" costs of VNS finally becoming clear.



Source: CMS, Capitol Policy Partners

- Third, blaming the recent jump on the absence of INSP data disregards the relative cost stability observed *prior* to the code combination. In fact, CMS claims data allows us to isolate the costs associated with each procedure both during and after that practice was used. The results suggest the net effect during this period was likely modest, and the subsequent spike stands out as anomalous relative to the well documented historic norm.



Source: CMS, Capitol Policy Partners

INSP vs LIVN: Read-Through If We're Wrong

As we recently outlined in our assessment of the likely coding and reimbursement scenarios available to INSP for its next generation Inspire V device, we believe LIVN is targeting the use of this legacy VNS code (CPT 64568) for its own hypoglossal nerve device for obstructive sleep apnea (OSA), expected to receive FDA approval 2H25. While it remains to be seen whether / how quickly existing Medicare OSA coverage policies can be updated to allow use of this code for such purposes, LIVN's efforts suggest an ancillary consideration may be to gain a facility reimbursement advantage relative to INSP, which is unlikely to shift from its current Level 5 APC group and $30K payment.

SCENARIO	INSP (64582)	LIVN (64568)	LIVN %Δ INSP
Procedure Costs	**$33,961**	**$44,127**	**30%**
Draft CY25 Payments	**$30,198**	**$30,198**	
Margin ($)	-$3,763	-$13,930	**0%**
Margin (%)	-11%	-32%	
HOP Panel #1 - New Level 6 APC	**$30,198**	**$41,560**	
Margin ($)	-$3,763	-$2,567	**38%**
Margin (%)	-11%	-6%	
HOP Panel #2 - New Tech APC	**$30,198**	**$45,001**	
Margin ($)	-$3,763	$873	**49%**
Margin (%)	-11%	2%	

Source: CMS, Capitol Policy Partners

We strongly suspect INSP would prefer to continue billing Inspire V under the company's existing CPT 64582 code, and this remains our base case, particularly in light of the higher *physician* reimbursement and the fact that all current coverage policies explicitly endorse that code for OSA while excluding the use of VNS code CPT 64568. This likely serves as a built-in extension of INSP's competitive moat, as we believe it would take LIVN 6-12 months to have these policies updated following FDA approval.

Should we be incorrect about INSP's ability to bill Inspire V under CPT 64582, however, its next best alternative would likely be to pursue use under VNS code CPT 64568, where a successful effort by LIVN to secure meaningfully higher *facility* payments would presumably put INSP into a difficult position:

1. It could *join* INSP and other competitors like **Nyxoah (NYXH)** in pushing MACs to cover that code for OSA, effectively ceding both their coverage advantage and the *physician* payment premium associated with CPT 64582; or

2. It could persist in its reliance on CPT 64582 while advocating *against* coverage of the VNS code to delay market entry, conceding a 40%+ *facility* payment disadvantage should those efforts be unsuccessful and relying instead on the *physician* rate premium to maintain volume / market share.

Between these we suspect INSP would choose Option (B), but a successful facility rate increase for LIVN this week is likely to force INSP to weigh two trade-offs with tangible downsides.

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