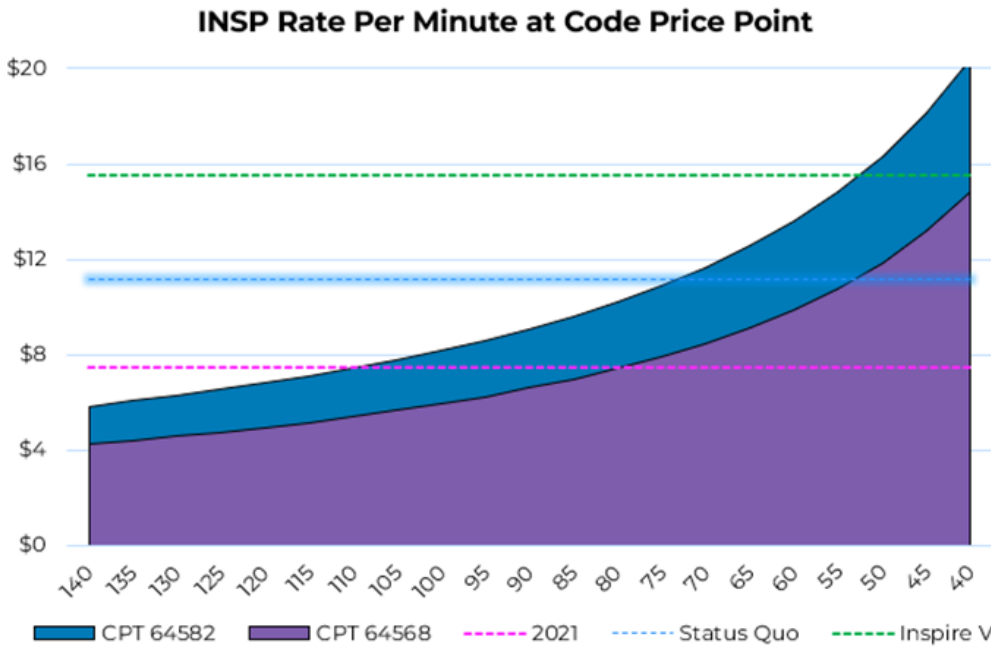
October 15, 2024

[INSP, LIVN, NYXH] Sleep Apnea: Codes, Coverage, & Value Accretion

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

Key Takeaways: We suspect **Inspire Medical's (INSP)** next-generation Inspire V implant procedure can secure Medicare coverage / reimbursement under the legacy product's billing code [CPT 64582: $816], where the shorter procedure time should increase physicians' rate per minute by ~30%. The longer-term risk is that this prompts a repricing analysis by CMS / American Medical Association (AMA) and a likely downward revision of the base rate. If payers balk at this code, the most likely alternative is to bill under the cranial nerve stimulation code [CPT 64568: $593], with per-minute payments staying relatively constant, despite the base rate itself being ~27% lower. The risk in that case would be a more streamlined coverage pathway for competitors **LivaNova (LIVN)** and **Nyxoah (NYXH)** following expected FDA approval of their respective devices.



Source: CMS, AMA, Capitol Policy Partners

Inspire Medical Systems Inc (INSP)	
Price:	$210.46
52-Week High:	$257.40
52-Week Low:	$123.00

LivaNova PLC (LIVN)	
Price:	$53.82
52-Week High:	$64.48
52-Week Low:	$42.75

Nyxoah (NYXH)	
Price:	$9.50
52-Week High:	$20.00
52-Week Low:	$4.00

Summary of Main Points

- INSP's current code was created in 2022 specifically to capture intrinsic differences between hypoglossal and vagus nerve stimulation as it relates to patient populations and surgical work intensity. That code therefore strikes us as the most appropriate option for Inspire V, even amid changes in procedure times and device hardware.

- Moreover, we view INSP's 2021 approval of a two-incision approach, rather than the original three that was used to create and value CPT 64582, as more of a significant deviation from the underlying procedure description than Inspire V's integrated pulse generator and sensing lead, and yet we are unaware of any significant claim denials or payer pushback from that experience.
- Given that average procedure times have fallen materially since the hypoglossal code was first created, we would not be surprised if the AMA / CMS were to reevaluate its Relative Value Unit (RVU) allocations in the next few years, risking a ~15% cut in the base rate, by our math. Alternatively, INSP could request only an "editorial revision" for the code's description to make it more applicable, though we suspect AMA would take the opportunity to resurvey code inputs as well.
- INSP could also seek a *new* temporary billing code to describe Inspire V, which would be priced by each individual Medicare Administrative Contractor (MAC), though we would have already expected to see movement on such an effort if that were indeed the plan.
- While CPT 64568 *did* previously serve as the "base procedure" for INSP's hypoglossal "add-on" service when it first came to market under temporary Category III code 0466T (2017-2022) [i.e., 64568 + 0466T], we think payers and specialty societies are unlikely to view that code as a more ideal option than the permanent hypoglossal code that was designed to replace it.
- Mitigating our confidence in this outcome, however, is the ongoing reluctance of INSP to directly confirm its billing plans for Inspire V, as well as the fact that LIVN appears to be targeting CPT 64568 for its own hypoglossal obstructive sleep apnea (OSA) implant [Aura 6000], expected to receive FDA approval by mid-2025.
- This would likely follow NYXH's Genio device for the same indication, where approval seems likely by 1Q25, though we suspect the company is targeting an historic neurostimulator *replacement* code [CPT 61886: $882].
- It should be noted that current MAC coverage policies do *not* list CPT 64568 or CPT 61886 as a covered code for de novo hypoglossal OSA implants, citing only the hypoglossal-specific CPT 64582 following its creation in 2022, meaning that any manufacturer seeking to use those codes would likely need to secure updated billing articles, if not a full coverage policy reconsideration.
- Billing article updates can likely be accomplished in 1-2 quarters following FDA-approval, whereas a full coverage policy review may take 1-2 years.

Procedure Billing Codes & Payment Rates

Recall that each billing code is intended to describe the physician work and cost inputs (e.g., time, capital) associated with a particular *procedure*, rather than a *device*. It was for this reason that, following INSP's initial FDA approval in 2014, a temporary "add-on" code [0466T: ~$400] was created – effective Jan. 1, 2017 – to describe the additional work associated with the company's hypoglossal OSA implant, beyond what was captured by base code CPT 64568 [2017: $677], which had to that point been used for *vagus* nerve stimulation in epilepsy treatment [*Description (2017): Incision for implantation of cranial nerve (eg, vagus nerve) neurostimulator electrode array and pulse generator*].

Accordingly, physicians performing INSP services were paid $677 for the "incision" and ~$400 for the "insertion of chest wall respiratory sensor electrode" and its "connection to pulse generator," for a total of nearly $1,100.

As the typical five-year expiration of this temporary code approached, the AMA agreed to create a single "primary procedure" code [CPT 64582] for identifying *hypoglossal* nerve stimulation services, effective Jan 1., 2022, while also changing the description of the base cranial nerve code [CPT 64582] to what it is today, shown below.

The new hyoglossal nerve code was then reviewed by the AMA's RVU Update Committee (RUC) in January 2021 before having its payment rate set by CMS in November 2021 [$888]. The corresponding payment rate represented a ~15% YoY decline for

INSP's OSA services, but a ~40% premium relative to the standalone vagus nerve code, with that delta staying largely constant through to today.

CODE	2024	2025 EST.	DESCRIPTION
64582	$837	$816	Open implantation of **hypoglossal nerve neurostimulator array, pulse generator**, and **distal respiratory sensor electrode or electrode array**
64568	$607	$593	Open implantation of **cranial nerve (eg, vagus nerve) neurostimulator electrode array** and **pulse generator**
0466T	Deleted 2022		Insertion of **chest wall respiratory sensor electrode or electrode array**, including connection to **pulse generator**

Source: CMS, AMA, Capitol Policy Partners

As explained by the AMA at the time of the code's creation (our emphasis):

*"The RUC thoroughly discussed CPT code 64568…and agreed that the use of this vagus nerve code only represents part of the work involved in hypoglossal nerve stimulator services and **does not address the distal inspiratory sensor**, which is for a **completely different site and incision**, as well as a **completely different disease process and patient population**…Hypoglossal nerve services are **very different** than the vagal nerve service in terms of patient population, **work intensity**, and risk."*

In other words, not only did the AMA agree that the CPT code set required a distinction to be made based on the anatomical differences between the two procedure types, but also the "intensity" of the associated work. Such a finding is key insofar as any procedure's RVU allocation – and therefore its payment – is largely a function of its Intensity of Work Unit Time (IWPUT) x total minutes. That RVU allocation is then multiplied by the Physician Fee Schedule (PFS) Conversion Factor, developed each year by CMS, to come up with a dollar payment amount.

By way of example, if two services have identical intra-service durations but different "intensity" levels, the one with the greater IWPUT would have a higher RVU allocation, and therefore reimbursement rate.

SERVICE	MINUTES	IWPUT	RVUs	CONVERSION FACTOR	PAYMENT RATE	RATE PER MINUTE
Service A	100	0.0633	6.33	$32.3562	$205	$2.05
Service B	100	0.0400	4.00		$129	$1.29

Source: Capitol Policy Partners

For the above example we selected the intra-procedural IWPUT for INSP's CPT 64582 and the vagus / cranial nerve CPT 64568, respectively, which also highlights the importance of the surgical time assessments that the AMA RUC and CMS assign to any given code. This is particularly the case given that – at the time such assignments are made – most services are relatively young, with physicians still early in the learning curve. As they grow more comfortable and procedure times fall, however, their compensation on a per-minute basis should increase commensurately. It is for this reason that CMS – with the assistance of the AMA – aims to reassess RVU allocations once every five years, though that is often not the case in practice.

AMA RUC / CMS SERVICE MINUTES	CPT 64582	CPT 64568
Assessment Year	**2021**	**2010**
Est. Reassessment	**2026**	**2015**
Pre-Service	69	51
Pre-Service Evaluation	*35*	*33*
Pre-Service Positioning	*20*	*3*
Pre-Service Scrub	*14*	*15*
Intra-Service	**140**	**90**
Hospital Post-Service	20	30
Other Hospital	19	58
Office Visits	46	46
TOTAL	**294**	**275**

Source: CMS, AMA, Capitol Policy Partners

Investors will likely note that: (A) clearly this reassessment target is not always met, as it has now been 14 years since CPT 64568 was reviewed; and (B) the 140 intra-service minutes for INSP's CPT 64582 would appear markedly higher than management commentary, which cites the current Inspire IV procedure time at 60-90 minutes, whereas the new Inspire V device is expected to reduce that to 45-60 minutes.

For (A) above, we would note that CPT 64568 is a relatively low volume service, with just ~250 Medicare fee-for-service (FFS) claims last year, compared to ~5,600 for CPT 64582.

For (B), it is important to recall two key considerations:

- The initial RUC analysis for INSP's code took place in Jan. 2021, with just ~500 services having taken place the prior year across ~30 different providers, indicating limited experience; and
- This relative value assessment was just prior to FDA approval of a revised procedural approach in March 2021, reducing the total number of associated incisions from three to two and procedure times by an average of 20%.

We have therefore assembled the below estimates for the typical INSP procedure times by year, based on management commentary, along with the average Medicare payment rate and how that translates into compensation on a per minute basis.

CPT 64582	2021	2022	2023	2024	2025 (Est.)
Intra-Service Minutes	**140**	**113**	**90**	**75**	**53**
%Δ YoY	--	-20%	-20%	-17%	-30%
%Δ Baseline	--	-20%	-36%	-46%	-63%
Average Payment	**$1,042**	**$888**	**$873**	**$837**	**$816**
Rate Per Minute	**$7.44**	**$7.89**	**$9.70**	**$11.15**	**$15.54**

Source: INSP, Capital Policy Partners

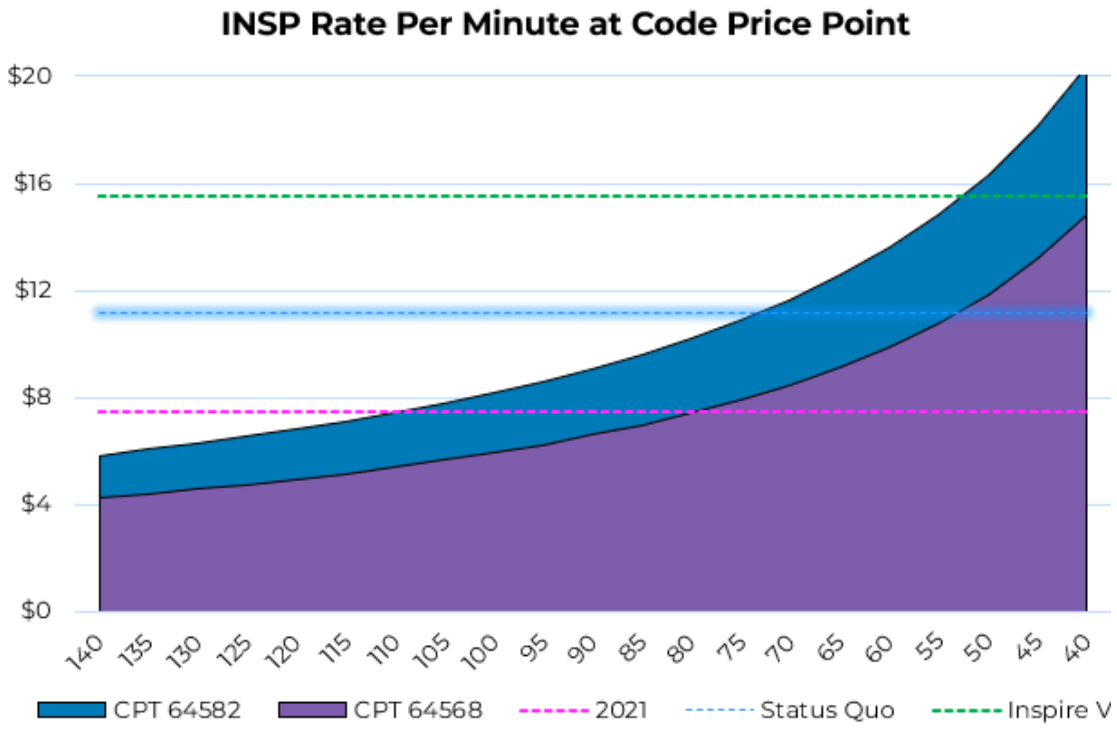
LIVN has not provided the same level of detail for its epilepsy device billing under CPT 64568, and – as noted above – neither CMS nor the AMA has reevaluated the code's physician time during this period, but we repeat this exercise using the intra-service minutes for ***INSP's*** procedure to demonstrate the per-minute reimbursement rate under different case times, should our expectations prove incorrect and the company ends up billing under this code as well.

SERVICE	2021	2022	2023	2024	2025 (Est.)
Procedure Minutes	**140**	**113**	**90**	**75**	**53**
%Δ YoY	--	-20%	-20%	-17%	-30%
%Δ Baseline	--	-20%	-36%	-46%	-63%
Average Payment	**$635**	**$628**	**$610**	**$607**	**$593**
Rate Per Minute	**$4.54**	**$5.58**	**$6.78**	**$8.09**	**$11.29**

Source: INSP, Capital Policy Partners

This shows how the median 30% decline in procedure times cited by management can result in a physician payment level that stays relatively constant, even if Inspire V cases must bill under this lower paying code.

To give a fuller picture, the below chart shows the per-minute rate for every procedure duration from 40 to 140 minutes under the reimbursement rates associated with both the current CPT 64582 and a hypothetical CPT 64568.



Source: CMS, AMA, Capitol Policy Partners

Service Descriptions / Vignettes

Equally important to determining whether any given service is appropriately described by a particular code is the procedure's "vignette," established by the AMA, which outlines the step-by-step processes involved in the associated intervention and – by extension – the physician work used to establish RVU allocations and payments.

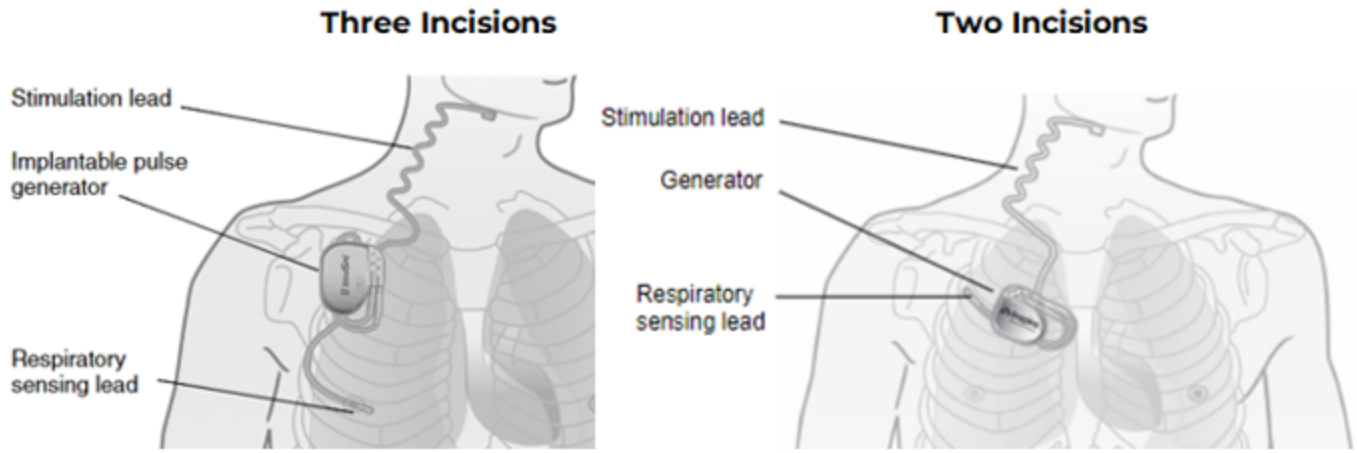
We provide the full vignette for INSP's current code below, while **emphasizing each step** and **the elements that are no longer present** following the company's approval of a two-incision approach in 2021. Beyond that, it is at this point unclear to us which, if any, procedure steps would not be required for the Inspire V device.

CPT 64582

Make an incision in the neck *and bring it through the platysma and dee fascia. Raise the subplatysmal flaps and identify and retract the submandibular gland. Identify and preserve the lingual nerve and marginal mandibular nerve. Take care to achieve meticulous hemostasis to avoid injuries to these, as well as the contents of the carotid sheath. Identify the posterior belly of the diagnostic muscle and identify the carotid artery through palpation. Identify the hypoglossal nerve by dissecting through the deep cervical fascia and following it distally until the branch(s) that extrudes the tongue is identified through electrical stimulation. A microscope is typically used to identify these distal branches.* ***Attach the stimulatory array to these distal branch(s)*** *and secure the stimulatory array to the digastric muscle.* ***Make an upper chest incision and create a pocket****. Bury the pulse generator in the created pocket and sew it to the pectoralis muscle.* ***Make a tunnel between the hypoglossal lead and the upper chest incision****.* ***Make a horizontal incision in the lateral chest wall****. Take the incision through the skin and subcutaneous tissue until the serratus anterior and pectoralis major muscles are identified. Proceed with dissection between these structures to the sixth intercostal space, identifying external and internal intercostal muscles. Extend blunt dissection between the intercostal muscles, avoiding the neurovascular bundle.* ***Place a sensor lead between the intercostal muscles*** *and secure it with multiple permanent sutures to the fascia overlying the chest wall.* ***Create a subcutaneous tunnel to connect the sensor-lead incision to the generator pocket****.* ***Attach the sensor lead to the generator*** *and verify the respiratory sensing. Reposition the sensor lead if the sensor waveform is not adequate. Irrigate all sites. Close the surgical incisions in a layered fashion and apply dressings.*

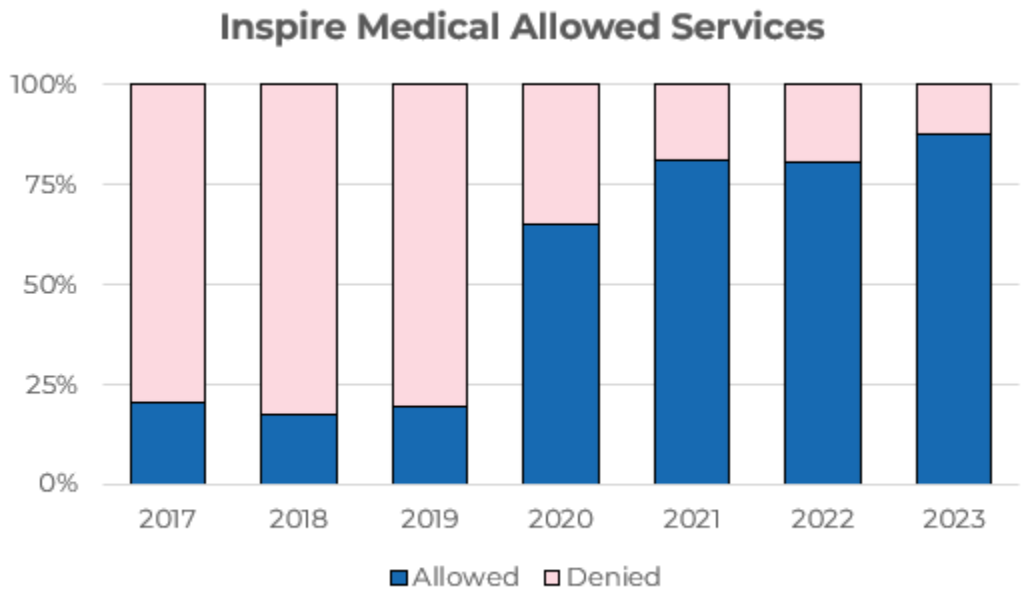
Source: AMA

As is clear above, the current code's procedure time assumptions are inclusive of three intra-service incisions, tunneling between the upper chest and the lateral chest wall, and sensor connection / testing, none of which is applicable to Inspire device models developed after March 2021.



Source: Inspire Medical

While the newly approved Inspire V device eliminates the standalone respirator pressure sensing lead and instead houses that capability within the implantable pulse generator itself, it maintains the broader two-incision approach that has to this point been deemed acceptable by payers without a meaningful increase in claim denials.



Source: Medicare claims data, Capitol Policy Partners

When comparing this with the topline description of CPT 64582 [*Open implantation of hypoglossal nerve neurostimulator array, pulse generator, and distal respiratory sensor electrode or electrode array*], we note that a respiratory sensor functionality ***is*** still being implanted via an open methodology, but the hardware's capabilities are now incorporated into the pulse generator.

This would therefore seem to leave the term "electrode" as the outstanding unknown in terms of whether payers interpret that to mean a physical standalone lead that is distally located or if it can refer to its broader functionality in the chest. Similar to the transition from three incisions to two, however, we suspect they will generally accept that perspective, with CPT 64582 continuing to strike us as a more appropriate code option than the cranial / vagus nerve set that describes an entirely distinct anatomical structure.

It is also important to highlight that there is no centralized authority that determines whether a given service may or may not be billed under a specific procedure code. It is instead up to each individual provider to select the code they feel is most appropriate relative to the service performed. Once a claim is submitted, each payer – both Medicare and commercial – has discretion to accept or reject its use.

It is for this reason that instructions from medical specialty societies – in this case the American Academy of Otolaryngology (AAO) – are highly relevant, as both providers and payers tend to follow their recommendations, and we await their guidance on not only Inspire V, but also NYXH's Genio and LIVN's Aura 6000, with the latter two expected to receive FDA approval by 1Q25 and mid-year, respectively. Unfortunately, there is no standard timeframe for when / if such public recommendations are provided.

Coding ≠ Coverage

Finding a permissible code, even if it has a defined payment amount, does not necessarily imply that payers will *accept* that code or the manner in which it is used, and in cases like hypoglossal nerve stimulation for the treatment of OSA, the permissible billing codes are already established by each individual MAC.

More specifically, CPT 64582 is the only code that is endorsed across all seven MAC jurisdictions for this purpose, with the previous cranial / vagus nerve code that had been used by INSP for 2017-2021 no longer recognized.

In fact, the only code outside of the unique hypoglossal set that appears in these policies – at least for three of the seven MACs – is CPT 61886 [*Insertion or replacement of cranial neurostimulator pulse generator or receiver, direct or inductive coupling; with connection to 2 or more electrode arrays*]. However, each of these three contractors makes clear – as does the AMA itself – that this is only to be used for the *replacement* of a neurostimulator device, as opposed to an initial implant.

CPT 61886	CY24	CY25-P
Base Rate	**$900**	**$882**
Intra-Service Minutes	*100*	*100*
Rate Per Minute	*$9.00*	*$8.82*

Source: CMS. Capitol Policy Partners

MAC	CY23 CLAIMS	% CLAIMS	CPT 64582	CPT 64568	CPT 61886
Novitas	1,474	26%	✔	✖	Replacement
Palmetto	908	16%	✔	✖	Replacement
Noridian	850	15%	✔	✖	✖
WPS	766	14%	✔	✖	✖
NGS	641	11%	✔	✖	✖
First Coast	585	10%	✔	✖	Replacement
CGS	355	6%	✔	✖	✖

Source: MAC Billing & Coding Articles, Capitol Policy Partners

With that being the case, providers / manufacturers seeking to bill under one of these alternative codes – as seems to be the case for LIVN with CPT 64582 and for NYXH with CPT 61886 – have two choices for securing *coverage* of their use for hypoglossal OSA implantation, where we view the latter as the more probable approach.

- **Billing & Coding Article Changes:** This can be accomplished via inclusion of these codes in MAC billing and coding articles, and can effectively take place at the contractors' discretion, as there is no requirement to give notice or accept public comments. Practically speaking, however, we suspect this would take 3-6 months following FDA approval, even if the MACs were open to the possibility, given the time needed to review an application, meet with stakeholders, and author / publish an update.
- **Full Coverage Reconsideration:** This would involve the MACs revisiting their existing LCDs to allow for the inclusion of newly approved technologies, as current policies are all reliant on data from INSP alone. Unlike the above approach, MACs are required to give public notice and accept / respond to comments, and as such the process typically take 5-7 months from the time an initial proposal is released. That draft policy would itself likely only be released 6+ months post-FDA approval given the need to review an application, parse the relevant clinical literature, consult with stakeholders, and author a coherent draft.

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.