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Inspire Medical (INSP): Medicare Rate Risks?

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We think Medicare physician reimbursement rates for **Inspire Medical's (INSP)** hypoglossal nerve sleep apnea system are likely to fall short of investor expectations, possibly even with a ~10%+ YoY *reduction*, as CMS prepares to release its CY22 Physician Fee Schedule (PFS) proposal in the coming days. Though we expect *facility* payments to stay relatively constant, PFS cuts would likely prove a headwind to volumes. While the apparent consensus that rates are likely to go *up* through the planned transition to a new Category I code [*645X1*] suggests potential mitigation we have not considered, and there is inherent uncertainty with making methodological assumptions, our extensive bottom-up analysis and discussions with high-volume surgeons indicate this will likely be difficult to achieve. In short, though Medicare is highly likely to pay surgeons a premium relative to the key vagus nerve reference code [*64568: $635*] from which we expect CMS will build the new hypoglossal-specific rates, the time and intensity inputs necessary to maintain constancy with current payments – inclusive of the soon-to-be-replaced Category III code [*0466T: $359-$455*] [TOTAL: *64568 + 0466T = $994-$1,090*] – seem likely to fall short of meeting, let alone exceeding, that baseline. This analysis is further supported through our work with outside consultants [*see supporting technical appendix here*].

STATE OF PLAY SUMMARY & SOLVING FOR X

As described in both company reimbursement materials and Medicare Administrative Contractor (MAC) coverage policies, physicians implanting INSP's Upper Airway Stimulation (UAS) therapy currently bill using a combination of two distinct codes that *must* be billed together:

TABLE 1

CODE	DESCRIPTION	NAT'L RATE / MAC AVG
64568	Incision for implantation of cranial nerve (e.g., vagus nerve) neurostimulator electrode array and pulse generator	$635
0466T	Insertion of chest wall respiratory sensor electrode or electrode array, including connection to pulse generator (List separately in addition to code for primary procedure)	*$359 / $455*
TOTAL		***$1,090 / $994***

****A volume-weighted average of MAC fee schedule rates for 0466T is $455.17, but a review of 2H20 claims data shows a significant number of instances where contractors pay only for the 64568 component of its combination with 0466T, skewing the national average down by almost $100.****

Because Medicare reimbursement is predicated on attributing Relative Value Units (RVUs) to any given procedure, which are then multiplied by a CMS-established "conversion factor" [*see more below*], set at 34.8931 for CY21, cumulative reimbursement of $994-$1,090 implies a need for 28.49 to 31.24 total RVUs to keep rates constant [e.g. $1,090 ÷ 34.8931 = 31.24]. The current vagus nerve procedure from which we expect Medicare will build the new code, however, has cumulative RVUs of 18.20, with *work-specific* RVUs of just 9.00, practice expense (PE) RVUs of 6.98, and malpractice (MP) RVUs of 2.22.

This means the agency must, through a combination of input assumptions measuring either surgical time or Intensity per Work Unit of Time (IWPUT), find at least 10 additional RVUs, a greater than 50% increase to the aggregate status quo already inclusive of pre- and post-operative work, as well as a more than 100% increase in the available work RVUs.

BASE CASE SUMMARY[1]

We describe / contextualize our methodology more fully down below, but our base case assumptions *do* involve a material increase in the "intensity" of the new hypoglossal implant code relative to its key reference codes identifying vagus nerve procedures [*up to 2x that baseline*], in addition to an intra-procedural time of 120-150 minutes, or up to 160% that of the underlying vagus nerve service.

TABLE 2

4.64 E&M RVUs, 2.22 MP RVUs, 51 MINS PRE-OP, 30 MINS POST-OP	IWPUT: 0.0439										
SCENARIO	**BASELINE**	**110%%**	**120%**	**130%**	**140%**	**150%**	**160%**	**170%**	**180%**	**190%**	**200%**
120 MINUTES INTRA-OP	$757	$784	$810	$837	$863	$890	$916	$943	$936	$996	$1,022
%Δ $1,090	-31%	-28%	-26%	-23%	-21%	-18%	-16%	-14%	-14%	-9%	-6%
%Δ $994	-24%	-21%	-18%	-16%	-13%	-10%	-8%	-5%	-6%	0%	3%
130 MINUTES INTRA-OP	$779	$808	$837	$866	$894	$923	$952	$980	$1,009	$1,038	$1,067
%Δ $1,090	-29%	-26%	-23%	-21%	-18%	-15%	-13%	-10%	-7%	-5%	-2%
%Δ $994	-22%	-19%	-16%	-13%	-10%	-7%	-4%	-1%	2%	4%	7%
140 MINUTES INTRA-OP	$802	$832	$863	$894	$925	$956	$987	$1,018	$1,049	$1,080	$1,111
%Δ $1,090	-26%	-24%	-21%	-18%	-15%	-12%	-9%	-7%	-4%	-1%	2%
%Δ $994	-19%	-16%	-13%	-10%	-7%	-4%	-1%	2%	6%	9%	12%
150 MINUTES INTRA-OP	$824	$857	$890	$923	$956	$989	$1,022	$1,056	$1,089	$1,122	$1,155
%Δ $1,090	-24%	-21%	-18%	-15%	-12%	-9%	-6%	-3%	0%	3%	6%
%Δ $994	-17%	-14%	-10%	-7%	-4%	0%	3%	6%	10%	13%	16%

Note also that we have built up this scenario analysis from the IWPUT inputs associated with a more complex and time-consuming vagus nerve neurostimulator *replacement* code [6456**9**], rather than those for the *initial insertion* [6456***8***], which INSP's service is currently billed under. While building from 64568 strikes us as more consistent with CMS methodology, we selected 64569 above to better illustrate the input assumptions necessary to reach the $1,090 / $994 status quo baseline.

Repeating this exercise using the IWPUT associated with 64568, however, results in materially lower rate outcomes, which we describe more fully down below:

4.64 E&M RVUs, 2.22 MP RVUs, 51 MINS PRE-OP, 30 MINS POST-OP	IWPUT: 0.0357										
SCENARIO	**BASELINE**	**110%%**	**120%**	**130%**	**140%**	**150%**	**160%**	**170%**	**180%**	**190%**	**200%**
120 MINUTES INTRA-OP	$708	$729	$751	$773	$794	$816	$837	$859	$880	$902	$923
%Δ $1,090	-35%	-33%	-31%	-29%	-27%	-25%	-23%	-21%	-19%	-17%	-15%
%Δ $994	-29%	-27%	-24%	-22%	-20%	-18%	-16%	-14%	-11%	-9%	-7%
130 MINUTES INTRA-OP	$726	$749	$773	$796	$819	$843	$866	$889	$913	$936	$959
%Δ $1,090	-33%	-31%	-29%	-27%	-25%	-23%	-21%	-18%	-16%	-14%	-12%
%Δ $994	-27%	-25%	-22%	-20%	-18%	-15%	-13%	-10%	-8%	-6%	-3%

[1] *Devised in consultation with Muller Consulting & Data Analytics (MCDA)*

140 MINUTES INTRA-OP	$744	$769	$794	$819	$844	$870	$895	$920	$945	$970	$995
%Δ $1,090	-32%	-29%	-27%	-25%	-23%	-20%	-18%	-16%	-13%	-11%	-9%
%Δ $994	-25%	-23%	-20%	-18%	-15%	-12%	-10%	-7%	-5%	-2%	0%
150 MINUTES INTRA0OP	$762	$789	$816	$843	$870	$896	$923	$950	$977	$1,004	$1,031
%Δ $1,090	-30%	-28%	-25%	-23%	-20%	-18%	-15%	-13%	-10%	-8%	-5%
%Δ $994	-23%	-21%	-18%	-15%	-12%	-10%	-7%	-4%	-2%	1%	4%

LOOKING GOOD ON THE SURFACE

While the *vagus* nerve service described by 64568 can be considered clinically similar to the *hypoglossal* nerve procedure used to implant INSP's UAS, in that they both target cranial nerves, the American Academy of Otolaryngology (AAO) notes that "the placement of the electrode array and pulse generator on the vagus nerve, as compared to the hypoglossal nerve, differs, with the latter procedure being more difficult and requiring more dissection of the nerve to identify those branches that protrude the tongue."

In other words, the INSP procedure has more work involved than its reference code and *should* therefore receive rates that are commensurately higher. Adding to this is the fact that – as described by Category III code 0466T above – the hypoglossal UAS procedure involves the *additional* step of inserting a chest wall sensor array.

We largely agree with this assessment, which led the American Medical Association (AMA) CPT Editorial Committee to endorse a new code to specifically describe the INSP procedure, effective Jan. 1, 2022, differentiating it from the vagus nerve reference code and, we believe, incorporating insertion of the respiratory sensor array that has previously been described by the legacy Category III code 0466T.

TABLE 3

DESCRIPTION	PANEL ACTION	EFFECTIVE DATE
Category III 0466T-0468T to Category I Hypoglossal Nerve Stimulator Services	Accepted addition of codes 645X1, 645X2, 645X3 to identify hypoglossal vs vagus nerve stimulator services, revision of codes 64568, 64575, 64580, 64581 to separately identify hypoglossal nerve stimulator services	January 1, 2022

AMA CPT Editorial Committee, Oct. 2020 Agenda

INSP takes the implications of this evaluation a step further in its 1Q21 call:

> ***QUESTION:*** *Just to level set ahead of this [new code and reimbursement proposal], because it may happen before your next earnings call, your expectation is that this payment is at or potentially slightly above where it was historically? Where it was historically, at least for Medicare, was call it $600 for the base payment…. and then the MACs have established $450, give-or-take, for 0466T. So $600 plus $450, just call it a little more than $1,000. Is that where you expect this July proposal to start?*
>
> ***ANSWER:*** *No, expect it to be higher, and the ENT society had all this data when they chose to submit. They had a choice, they could either just convert 0466T to a Category I code and lock in that payment, but they looked at it and determined the work for a hypoglossal nerve implant is more extensive than a vagal nerve implant. And that $600 to $800 was undervalued. And so they went to create a whole new code set, one that they could work directly with CMS to establish payment. So I would expect that number to be higher.*

While it is certainly likely that INSP's new code will be priced above its vagus nerve reference procedure [64568] due to its higher level of physician work / time / difficulty, a recreation of CMS's rate-setting methodology suggests that the inputs necessary to set *enough* of a premium to maintain – let alone exceed – payment levels through the current *combination* of 64568 + 0466T are likely excessive relative to past precedent and the "intensity" associated with this baseline, known as the Intensity Per Work Unit of Time (IWPUT).

Our estimates suggest that the IWPUT associated with the vagus nerve reference code would likely need to increase by a factor of 1.6x to 2.0x for the average INSP procedure [*approximately 120-150 intra-service minutes*] to be held harmless relative to the status quo.

GETTING "INTENSE" ABOUT "WORK"

RVUs representing a procedure's core inputs are themselves segregated into three distinct buckets:

TABLE 4

RELATIVE VALUE UNITS (RVUs)	
WORK RVUs	The portion used in furnishing the service that reflects physician time and intensity, where the **pre-service**, **intra-operative**, and **post-service** minutes are multiplied by the **Intensity Per Work Unit of Time (IWPUT)**. As outlined in CMS's CY21 final rule (p. 126), **"pre-service evaluation time and post-service time both have a long-established IWPUT of 0.0224,"** to which is also added more general **Evaluation and Management (E&M)** post-surgical follow-up time (i.e. post-operative check-ups), leaving the **intra-operative** portion as the most relevant variable in distinguishing the relative "work" between procedures.
PRACTICE EXPENSE (PE) RVUs	The **direct** and **indirect** practice resources involved in furnishing each service, where direct expenses include clinical labor, medical supplies, and medical equipment, while indirect expenses involve administrative labor, office expenses, and all other expenses. Because many of these costs are borne by facilities (e.g. hospitals, ASCs), the facility-based PE RVU allowance is typically lower than it is for office-based procedures.
MALPRACTICE (MP) RVUs	Typically the smallest component of the RVU values, these represent **professional liability expenses** and the **risk of litigation** associated with underlying services, based on commercial and physician-owned premium data from all 50 states.

While PE and MP RVU values can vary to some degree (at a ratio of roughly 1 work RVU to ~0.44 PE RVUs) based on a physician's time away from the office or the involvement of other clinical personnel, the most important variable in assessing a procedure's "work" or "intensity" is of course the "*work* RVU" input. As the term "Relative Value Unit" implies, CMS sets these levels *relative* to other procedures within a given code set and/or the broader PFS, applying an IWPUT score to the intra-procedural minutes assigned to the service.

QUANTIFYING INTENSITY

While CMS does not publish intensity calculations for individual codes as part of its annual data files, comments submitted by the AMA's Relative Value Scale Update Committee (RUC) in response to the CY21 PFS proposal last summer *do* specify the IWPUT score for an associated – and more complex / higher-paying – code within the vagus nerve procedure family [*6456***9**]:

TABLE 5

CPT 64569	
Revision or replacement of cranial nerve (eg, vagus nerve) neurostimulator electrode array, including connection to existing pulse generator	
Intra-Service Work Per Unit of Time (IWPUT)	**0.0439**
COMPONENT	**MINUTES**
Pre-Operative	
Pre-Service Evaluation	40
Dress, Scrub, & Wait	15
Other Pre-Service	3
Intra-Service	120
Same-Day Post-Service Time	30
SUB-TOTAL: DAY OF SURGERY TIME	*208*
ICU Time After Day of Surgery	N/A
Post-Op Hospital Time After Day of Surgery	58
Office Visit Time	46
SUB-TOTAL: POST-SURGICAL TIME	*104*
TOTAL	**312**
RELATIVE VALUE UNITS	
Work RVUs	11.00
Practice Expense (PE) RVUs	8.19
Malpractice (MP) RVUs	3.29
TOTAL	**22.48**
NATIONAL REIMBURSEMENT RATE	**$784.40**

Though the RUC's comments focus on CMS having disregarded its rate recommendation for an unrelated procedure [*19380: $826.97, work RVUs: 11.17, intra-service time: 120 mins*], the Committee takes particular aim at the agency's use of the above "very low intensity" vagus nerve code as a reference:

> *The current IWPUT for 19380 is inappropriate for a relatively intense major surgical procedure, at only 0.0492, which strongly implies the current times are inflated relative to the current work RVU and not valid for comparison to the new times….The reference code that CMS used to support their proposed value, CPT code 64569, Revision or replacement of cranial nerve (eg, vagus nerve) neurostimulator electrode array, including connection to existing pulse generator (work RVU= 11.00, intra-service time of 120 minutes, total time of 312 minutes), is not a strong reference code as it has a very low intensity for a major surgical procedure (IWPUT = 0.0439) and has highly disparate physician work from the survey code.*

CMS was not swayed in its final CY21 regulation, however, establishing work RVUs *below* RUC recommendations [*11.17 vs 12.00*] and noting the following, which we view as informative for how the agency is likely to view the selection of appropriate reference codes for INSP's hypoglossal implant procedure:

> *We are statutorily obligated to consider both time and intensity in establishing work RVUs for PFS services. Additionally, we use other methods to validate work RVUs, such as reference codes. When using referencing codes to support a proposed work RVU, we do not consider there to be a direct "cross-walk" between the CPT code that is being revalued and the chosen reference code. Instead, it is meant to be supportive in validating work times. We continue to believe that the relative value system of the PFS is such that all services are appropriately subject to comparisons to one another. We do not agree that codes must share the same patient population or utilization level to serve as an appropriate reference code. We also recognize that it is important to use recent available data regarding work times. However, we believe that while some reference code values may be considered older, they still provide support for revision of work RVUs when survey times show a marked increase or decrease in total and intra-service time, as was the case for this code family.*

With such steadfast pushback to criticism over the use of a neurostimulator as a reference codewe think it similarly likely that CMS will maintain this baseline in its pricing of a new addition to this specific code set, particularly given accumulated claims data through current requirements that they be billed together with 0466T.

IS "VERY LOW INTENSITY" STILL TOO HIGH?

While we have selected the intra-service IWPUT from 6456***9*** as our proxy [0.0439], which we increase even more significantly through our scenario analyses down below [*from baseline to 2x*], even this reference point is likely high relative to the intensity score for the *actual* companion code for INSP's device, 6456***8***, which we estimate at 0.0357].

As discussed in AMA CPT coding articles following the initial release of these codes [Feb. 2011]:

> *When a new cranial nerve stimulator is placed, the surgeon always performs two services: the insertion of the cranial neurostimulator pulse generator or receiver and the incision for the implantation of the neurostimulator electrode. Both procedures are now identified by a single code, 64568…..The revision or replacement of a cranial nerve stimulator electrode array is usually performed with revision of the pulse generator, as the pulse generator needs to be removed from the subcutaneous pocket for connection to the new electrode array. Code 64569 is reported to identify both parts of this procedure. Because* ***the work of a revision procedure is significantly more complex and time intensive than the work involved in implanting a cranial nerve stimulator electrode array for the first time****, a separate code is used to distinguish the revision procedure.* [our emphasis]

Our baseline assumptions may therefore already reflect "significantly more" complexity and time intensity than CMS's most likely reference procedure, if not the ultimate time allowed for the hypoglossal implant.

The IWPUT for 64568 itself can be reverse engineered by removing the work RVU assignments for the pre-, intra-, and post-service aspects of the procedure, resulting in an intensity score of 0.0357, where CMS's own data outline the following service-specific input breakdown:

TABLE 6

CPT 64568	
Incision for implantation of cranial nerve (eg, vagus nerve) neurostimulator electrode array and pulse generator	
Intra-Service Work Per Unit of Time (IWPUT) [*EST.*]	0.0357
COMPONENT	**MINUTES**
Pre-Operative	
Pre-Service Evaluation	33
Dress, Scrub, & Wait	15
Other Pre-Service	3
Intra-Service	90
Same-Day Post-Service Time	30
SUB-TOTAL: DAY OF SURGERY TIME	*171*
ICU Time After Day of Surgery	N/A
Post-Op Hospital Time After Day of Surgery	58
Office Visit Time	46
SUB-TOTAL: POST-SURGICAL TIME	*104*
TOTAL	**275**
RELATIVE VALUE UNITS	
Work RVUs	9.00
Practice Expense (PE) RVUs	6.98
Malpractice (MP) RVUs	2.22
TOTAL	**18.20**
NATIONAL REIMBURSEMENT RATE	**$635.05**

While we have run analyses using this lower baseline IWPUT as well, resulting in even more negative outcomes [*see below*], the 0.0439 IWPUT associated with the more intensive / complex revision code strikes us as a more appropriate baseline given its greater similarity to INSP within the broader neurostimulator coding segment, in terms of intra-service procedure time and the inherent RVU premium already baked into its construction. We should also note that this code has materially higher liability / MP RVUs [3.29] than any other within this code set, including 64568 [2.22], boosting its overall rate valuation.

In fact, both codes are already in the 90th percentile of the *entire* PFS in terms of their MP RVU assignments, making it unlikely that CMS will boost this side of the ledger to bolster rates. The same holds true for the global Evaluation & Management (E&M) contribution to work RVUs, where 64569 and 64568 are in the 75th percentile [each at 4.29 for CY21], suggesting little room for upward revisions there as well.

If our base case turns out to be incorrect, it is therefore likely that it will be due to our IWPUT and/or intra-operative time assumptions, particularly as we acknowledge that the AMA-cited intensity score certainly appears low relative to the underlying procedure(s).

One potential explanation for this would be that not all intra-operative minutes are created equal, as there can be long periods of routine punctuated by short intervals requiring greater technical skill, netting out to a low aggregate IWPUT as a function of the overall procedure time.

To provide greater context of these inputs we list the PFS's neurostimulator coding section below:

TABLE 7: RELATIVE VALUE UNITS

CODE	DESCRIPTION	WORK RVUs	PE RVUs	MP RVUs	TOTAL	CY21 RATE	GLOBAL SRVC DAYS
64553	Implant neuroelectrodes	6.13	3.71	0.77	10.61	$370.22	10
64555	Implant neuroelectrodes	5.76	3.42	0.77	9.95	$347.19	10
64561	Implant neuroelectrodes	5.44	2.74	0.69	8.87	$309.50	10
64566	Neuroeltrd stim post tibial	0.60	0.21	0.09	0.90	$31.40	-
64568	Inc for vagus n elect impl	9.00	6.98	2.22	18.20	$635.05	90
64569	Revise/repl vagus n eltrd	11.00	8.19	3.29	22.48	$784.40	90
64570	Remove vagus n eltrd	9.10	9.22	3.39	21.71	$757.53	90
64575	Implant neuroelectrodes	4.42	4.42	1.02	9.86	$344.05	90
64580	Implant neuroelectrodes	4.19	4.05	1.03	9.27	$323.46	90
64581	Implant neuroelectrodes	12.20	5.51	1.59	19.30	$673.44	90
64585	Revise/remove neuroelectrode	2.11	1.82	0.27	4.20	$146.55	10
64590	Insrt/redo pn/gastr stimul	2.45	1.92	0.34	4.71	$164.35	10
64595	Revise/rmv pn/gastr stimul	1.78	1.69	0.25	3.72	$129.80	10
MINIMUM		**0.60**	**0.21**	**0.09**	**0.90**	**$31.40**	
MEDIAN		**5.44**	**3.71**	**0.77**	**9.92**	**$344.05**	
AVERAGE		**5.71**	**4.14**	**1.21**	**11.06**	**$385.92**	
MAXIMUM		**12.20**	**9.22**	**3.39**	**24.81**	**$784.40**	

TABLE 8: OVERALL SERVICE TIME (MINUTES)

	PRE-OPERATIVE							
CODE	PRE-OP EVALUATION	PRE-OP POSITIONING	PRE-OP SCRUB & DRESS	PRE-SERVICE TOTAL	INTRA-OP SERVICE	IMMEDIATE POST-OP	DAY OF SURGERY TOTAL	E&M TIME
64553	18	1	6	25	75	18	118	42
64555	18	1	6	25	60	18	103	42
64561	22	5	0	27	45	19	91	40
64566	7	0	0	7	10	5	22	0
64568	33	3	15	51	90	30	171	104
64569	40	3	15	58	120	30	208	104
64570	40	3	15	58	90	30	178	104
64575	12	0	0	12	30	12	178	24
64580	11	0	0	11	33	11	55	24
64581	60	0	0	60	120	30	210	59
64585	9	0	0	9	24	9	42	16
64590	12	0	0	12	34	12	58	16
MINIMUM	**7.00**	**0.00**	**0.00**	**7.00**	**10.00**	**5.00**	**22.00**	**0.00**
MEDIAN	**18.00**	**0.50**	**0.00**	**25.00**	**52.50**	**18.00**	**110.50**	**41.00**
AVERAGE	**23.50**	**1.33**	**4.75**	**29.58**	**60.92**	**18.67**	**119.50**	**47.92**
MAXIMUM	**60.00**	**5.00**	**15.00**	**60.00**	**120.00**	**30.00**	**210.00**	**104.00**

Building up from these time / intensity assumptions, high-volume surgeons have suggested that the INSP implant is only ~1/3 more time consuming and "intense" than the underlying vagus procedure described by *64568*, indicating that its lower IWPUT of 0.0357 may in fact be a more appropriate baseline than our use of that from 64569 [0.0439] above, which we chose as a more aggressive assumption to show the difficulties INSP may have in achieving rates consistent with the status quo baseline. If CMS were to use this lower IWPUT, final rates would likely fall below even our base case. We outline the probable outcome of such a baseline in Table 9 below, increasing the procedure's intensity by up to 100%, well above the 1/3 described by providers.

TABLE 9: IWPUT OF 0.0357

4.64 E&M RVUs, 2.22 MP RVUs, 51 MINS PRE-OP, 30 MINS POST-OP	IWPUT: 0.0357										
SCENARIO	**BASELINE**	**110%%**	**120%**	**130%**	**140%**	**150%**	**160%**	**170%**	**180%**	**190%**	**200%**
120 MINUTES INTRA-OP	$708	$729	$751	$773	$794	$816	$837	$859	$880	$902	$923
%Δ $1,090	-35%	-33%	-31%	-29%	-27%	-25%	-23%	-21%	-19%	-17%	-15%
%Δ $994	-29%	-27%	-24%	-22%	-20%	-18%	-16%	-14%	-11%	-9%	-7%
130 MINUTES INTRA-OP	$726	$749	$773	$796	$819	$843	$866	$889	$913	$936	$959
%Δ $1,090	-33%	-31%	-29%	-27%	-25%	-23%	-21%	-18%	-16%	-14%	-12%
%Δ $994	-27%	-25%	-22%	-20%	-18%	-15%	-13%	-10%	-8%	-6%	-3%
140 MINUTES INTRA-OP	$744	$769	$794	$819	$844	$870	$895	$920	$945	$970	$995
%Δ $1,090	-32%	-29%	-27%	-25%	-23%	-20%	-18%	-16%	-13%	-11%	-9%
%Δ $994	-25%	-23%	-20%	-18%	-15%	-12%	-10%	-7%	-5%	-2%	0%
150 MINUTES INTRA0OP	$762	$789	$816	$843	$870	$896	$923	$950	$977	$1,004	$1,031
%Δ $1,090	-30%	-28%	-25%	-23%	-20%	-18%	-15%	-13%	-10%	-8%	-5%
%Δ $994	-23%	-21%	-18%	-15%	-12%	-10%	-7%	-4%	-2%	1%	4%

WORK AS A FUNCTION OF PROCEDURE TIMES (120-150 MINUTES)

In announcing FDA approval of its new two-incision approach to implantation on March 15, INSP notes that this "yielded a statistically significant decrease in surgical time, to just under 100 minutes on average, which is a 26-minute reduction from the three-incision procedure time." While the company similarly maintains that more than 90% of implants now utilize this shorter-duration approach, it nevertheless implies a baseline procedure time of 126 minutes.

That timeframe is largely consistent with the 120 intra-operative minutes allowed by CMS for reference code 64569, as well as clinical literature on the subject. A July 2018 study in the journal *Respiratory Medicine* finds that, "in general, the [INSP] implantation is completed in about 90-120 minutes." This is also in keeping with our own conversations with high-volume surgeons.

Describing what we view as the higher end of the intra-operative range is a Sept. 2020 analysis in the *Annals of Otology, Rhinology & Laryngology* showing "the median operative time dropping from 150 minutes for the first 10 implants to 134 minutes for the subsequent 10 implants."

We therefore use 150 minutes as the top end of our analysis.

While any reduction in real-world surgical times would also allow providers to perform a larger number of procedures per day, improving out-of-office economics relative to other alternatives, this allows what we view as an effective range of procedure work time that, combined with the IWPUT assumptions above, likely works against INSP in gleaning a CY22 reimbursement rate that meets / exceeds current year baselines [*$1,090 / $994*].

SCENARIO ANALYSES: LOOKING FOR A 1.6x to 2.0x MULTIPLIER

While we use the IWPUT associated with 64569 below as our baseline intensity assumption, increasing its value by up to 2.0x, we also apply variations of the service-related minutes and PE / RVU assignments. Given the importance of solving for the net ~30 RVUs needed to keep rates constant, our models also account for crossover effects in PE RVUs due to increasing work intensity and time.[2]

CPT 64568
Incision for implantation of cranial nerve (eg, vagus nerve) neurostimulator electrode array and pulse generator

CPT 64569
Revision or replacement of cranial nerve (eg, vagus nerve) neurostimulator electrode array, including connection to existing pulse generator

[2] *PE RVUs increase at a rate of 0.44194893 for every 1 work RVU*

Intra-Service Work Per Unit of Time (IWPUT) [*EST.*]	0.0357
COMPONENT	**MINUTES**
Pre-Operative	
Pre-Service Evaluation	33
Dress, Scrub, & Wait	15
Other Pre-Service	3
Intra-Service	90
Same-Day Post-Service Time	30
SUB-TOTAL: DAY OF SURGERY TIME	*171*
ICU Time After Day of Surgery	N/A
Post-Op Hospital Time After Day of Surgery	58
Office Visit Time	46
SUB-TOTAL: POST-SURGICAL TIME	*104*
TOTAL	**275**
RELATIVE VALUE UNITS	
Work RVUs	9.00
Practice Expense (PE) RVUs	6.98
Malpractice (MP) RVUs	2.22
TOTAL	**18.20**
NATIONAL REIMBURSEMENT RATE	**$635.05**

Intra-Service Work Per Unit of Time (IWPUT)	0.0439
COMPONENT	**MINUTES**
Pre-Operative	
Pre-Service Evaluation	40
Dress, Scrub, & Wait	15
Other Pre-Service	3
Intra-Service	120
Same-Day Post-Service Time	30
SUB-TOTAL: DAY OF SURGERY TIME	*208*
ICU Time After Day of Surgery	N/A
Post-Op Hospital Time After Day of Surgery	58
Office Visit Time	46
SUB-TOTAL: POST-SURGICAL TIME	*104*
TOTAL	**312**
RELATIVE VALUE UNITS	
Work RVUs	11.00
Practice Expense (PE) RVUs	8.19
Malpractice (MP) RVUs	3.29
TOTAL	**22.48**
NATIONAL REIMBURSEMENT RATE	**$784.40**

The below summary tables identify what we view as the most probable range of outcomes as part of CMS's CY22 PFS proposal. Each is displayed to demonstrate the implied reimbursement and its percent change relative to: (1) the combined amounts of the full CMS and MAC fee schedule payment amounts for 64568 + 0466T [$1,090]; and (2) observed claims data [$994]. Both of these baselines are described in Table 1 above. This is followed by a scenario analysis chart outlining what manner of assumptions would be necessary to maintain rates at breakeven levels

SCENARIO #1

IWPUT BASELINE: 0.0439
51 MINUTES OF PRE-OPERATIVE WORK (CONSISTENT WITH 64568)
30 MINUTES OF POST-OPERATIVE WORK (CONSISTENT WITH 64568)
4.64 POST-OPERATIVE E&M WORK RVUs (CONSISTENT WITH 64569 UPDATED to 2021 RVUs)
MALPRACTICE RVUs: 2.22 (CONSISTENT WITH 64568)
PRACTICE EXPENSE DIRECT COSTS: $68.48 (CONSISTENT WITH 64568)

4.64 E&M RVUs, 2.22 MP RVUs, 51 MINS PRE-OP, 30 MINS POST-OP	IWPUT: 0.0439										
SCENARIO	**BASELINE**	**110%%**	**120%**	**130%**	**140%**	**150%**	**160%**	**170%**	**180%**	**190%**	**200%**
120 MINUTES INTRA-OP	$757	$784	$810	$837	$863	$890	$916	$943	$936	$996	$1,022
%Δ $1,090.22	-31%	-28%	-26%	-23%	-21%	-18%	-16%	-14%	-14%	-9%	-6%
%Δ $993.57	-24%	-21%	-18%	-16%	-13%	-10%	-8%	-5%	-6%	0%	3%
130 MINUTES INTRA-OP	$779	$808	$837	$866	$894	$923	$952	$980	$1,009	$1,038	$1,067
%Δ $1,090.22	-29%	-26%	-23%	-21%	-18%	-15%	-13%	-10%	-7%	-5%	-2%
%Δ $993.57	-22%	-19%	-16%	-13%	-10%	-7%	-4%	-1%	2%	4%	7%

140 MINUTES INTRA-OP	$802	$832	$863	$894	$925	$956	$987	$1,018	$1,049	$1,080	$1,111
%Δ $1,090.22	-26%	-24%	-21%	-18%	-15%	-12%	-9%	-7%	-4%	-1%	2%
%Δ $993.57	-19%	-16%	-13%	-10%	-7%	-4%	-1%	2%	6%	9%	12%
150 MINUTES INTRA-OP	$824	$857	$890	$923	$956	$989	$1,022	$1,056	$1,089	$1,122	$1,155
%Δ $1,090.22	-24%	-21%	-18%	-15%	-12%	-9%	-6%	-3%	0%	3%	6%
%Δ $993.57	-17%	-14%	-10%	-7%	-4%	0%	3%	6%	10%	13%	16%

SCENARIO #2

IWPUT BASELINE: 0.0439
60 MINUTES OF PRE-OPERATIVE WORK (CONSISTENT WITH 64569)
60 MINUTES OF POST-OPERATIVE WORK (2x THAT WITH 64569)
4.64 POST-OPERATIVE E&M WORK RVUs (CONSISTENT WITH 64569 UPDATED TO 2021 RVUs)
MALPRACTICE RVUs: 3.29 (CONSISTENT WITH 64569)
PRACTICE EXPENSE DIRECT COSTS: $68.48 (CONSISTENT WITH 64568)

4.64 E&M RVUs, 3.29 MP RVUs, 60 MINS PRE-OP, 60 MINS POST-OP	IWPUT: 0.0439

SCENARIO	BASELINE	110%%	120%	130%	140%	150%	160%	170%	180%	190%	200%
120 MINUTES INTRA-OP	$839	$865	$892	$918	$945	$971	$998	$1,024	$1,051	$1,077	$1,104
%Δ $1,090.22	-23%	-21%	-18%	-16%	-13%	-11%	-8%	-6%	-4%	-1%	1%
%Δ $993.57	-16%	-13%	-10%	-8%	-5%	-2%	0%	3%	6%	8%	11%
130 MINUTES INTRA-OP	$861	$889	$918	$947	$976	$1,004	$1,033	$1,062	$1,090	$1,119	$1,148
%Δ $1,090.22	-21%	-18%	-16%	-13%	-11%	-8%	-5%	-3%	0%	3%	5%
%Δ $993.57	-13%	-10%	-8%	-5%	-2%	1%	4%	7%	10%	13%	16%
140 MINUTES INTRA-OP	$883	$914	$945	$976	$1,007	$1,037	$1,068	$1,099	$1,130	$1,161	$1,192
%Δ $1,090.22	-19%	-16%	-13%	-11%	-8%	-5%	-2%	1%	4%	7%	9%
%Δ $993.57	-11%	-8%	-5%	-2%	1%	4%	8%	11%	14%	17%	20%
150 MINUTES INTRA-OP	$905	$938	$971	$1,004	$1,037	$1,071	$1,104	$1,137	$1,170	$1,203	$1,236
%Δ $1,090.22	-17%	-14%	-11%	-8%	-5%	-2%	1%	4%	7%	10%	13%
%Δ $993.57	-9%	-6%	-2%	1%	4%	8%	11%	14%	18%	21%	24%

SCENARIO #3

IWPUT BASELINE: 0.0357
51 MINUTES OF PRE-OPERATIVE WORK (CONSISTENT WITH 64569)
30 MINUTES OF POST-OPERATIVE WORK (2x THAT WITH 64569)
4.64 POST-OPERATIVE E&M WORK RVUs (CONSISTENT WITH 64569 UPDATED TO 2021 RVUs)
MALPRACTICE RVUs: 2.22 (CONSISTENT WITH 64568)
PRACTICE EXPENSE DIRECT COSTS: $68.48 (CONSISTENT WITH 64568)

4.64 E&M RVUs, 2.22 MP RVUs, 51 MINS PRE-OP, 30 MINS POST-OP	IWPUT: 0.0357

SCENARIO	BASELINE	110%%	120%	130%	140%	150%	160%	170%	180%	190%	200%
120 MINUTES INTRA-OP	$708	$729	$751	$773	$794	$816	$837	$859	$880	$902	$923
%Δ $1,090.22	-35%	-33%	-31%	-29%	-27%	-25%	-23%	-21%	-19%	-17%	-15%
%Δ $993.57	-29%	-27%	-24%	-22%	-20%	-18%	-16%	-14%	-11%	-9%	-7%
130 MINUTES INTRA-OP	$726	$749	$773	$796	$819	$843	$866	$889	$913	$936	$959
%Δ $1,090.22	-33%	-31%	-29%	-27%	-25%	-23%	-21%	-18%	-16%	-14%	-12%

%Δ $993.57	-27%	-25%	-22%	-20%	-18%	-15%	-13%	-10%	-8%	-6%	-3%
140 MINUTES INTRA-OP	$744	$769	$794	$819	$844	$870	$895	$920	$945	$970	$995
%Δ $1,090.22	-32%	-29%	-27%	-25%	-23%	-20%	-18%	-16%	-13%	-11%	-9%
%Δ $993.57	-25%	-23%	-20%	-18%	-15%	-12%	-10%	-7%	-5%	-2%	0%
150 MINUTES INTRA0OP	$762	$789	$816	$843	$870	$896	$923	$950	$977	$1,004	$1,031
%Δ $1,090.22	-30%	-28%	-25%	-23%	-20%	-18%	-15%	-13%	-10%	-8%	-5%
%Δ $993.57	-23%	-21%	-18%	-15%	-12%	-10%	-7%	-4%	-2%	1%	4%

SCENARIO #5

IWPUT BASELINE: 0.0357
51 MINUTES OF PRE-OPERATIVE WORK (CONSISTENT WITH 64569)
30 MINUTES OF POST-OPERATIVE WORK (2x THAT WITH 64569)
4.64 POST-OPERATIVE E&M WORK RVUs (CONSISTENT WITH 64569 UPDATED TO 2021 RVUs)
MALPRACTICE RVUs: 3.29 (CONSISTENT WITH 64569)
PRACTICE EXPENSE DIRECT COSTS: $68.48 (CONSISTENT WITH 64568)

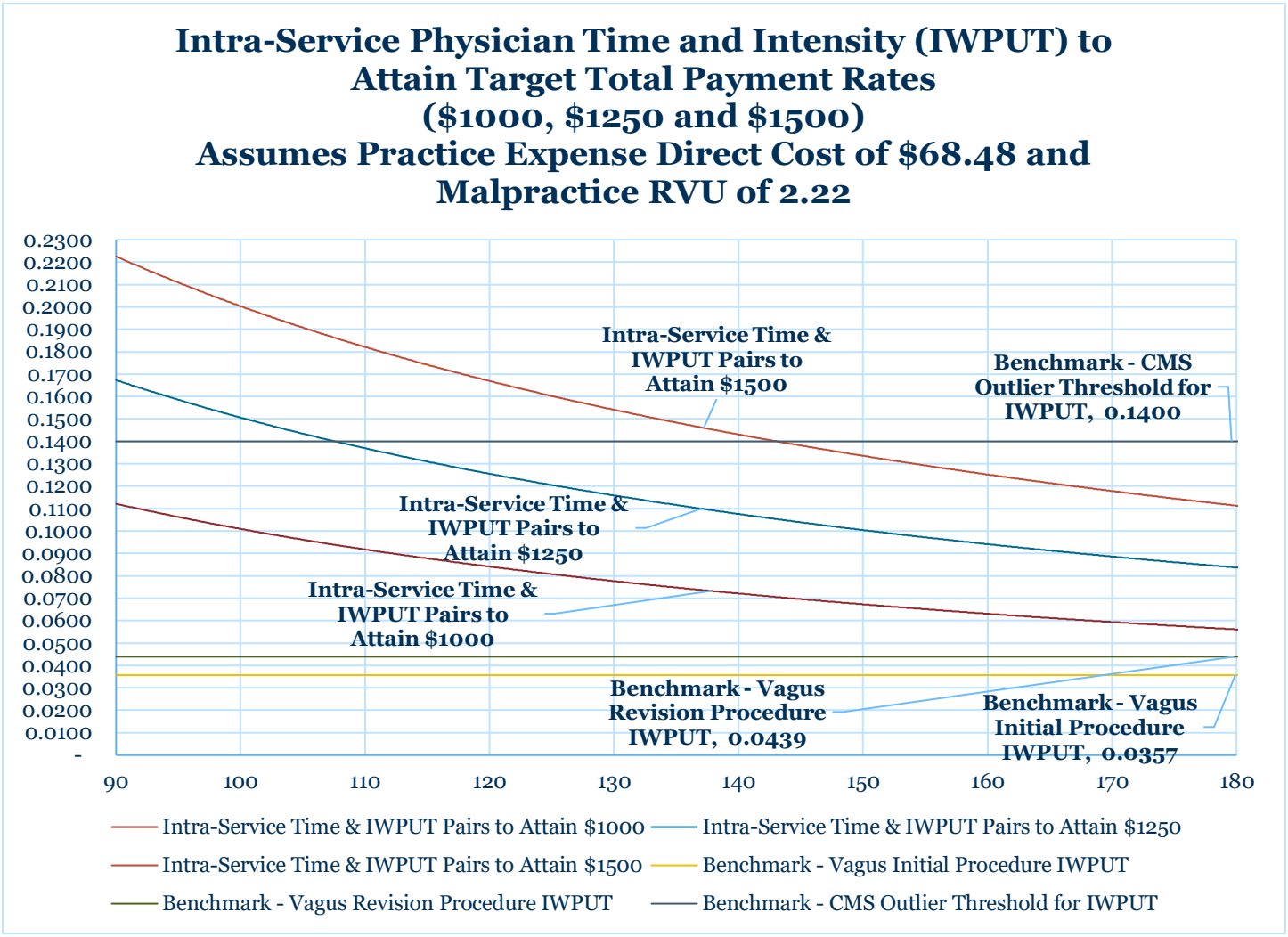
4.64 E&M RVUs, 3.29 MP RVUs, 51 MINS PRE-OP, 30 MINS POST-OP	IWPUT: 0.0357									
SCENARIO	**BASELINE**	**110%%**	**120%**	**130%**	**140%**	**150%**	**160%**	**170%**	**180%**	**190%**	**200%**
120 MINUTES INTRA-OP	$789	$811	$832	$854	$875	$897	$918	$940	$962	$983	$1,005
%Δ $1,090.22	-28%	-26%	-24%	-22%	-20%	-18%	-16%	-14%	-12%	-10%	-8%
%Δ $993.57	-21%	-18%	-16%	-14%	-12%	-10%	-8%	-5%	-3%	-1%	1%
130 MINUTES INTRA-OP	$807	$830	$854	$877	$901	$924	$947	$971	$994	$1,017	$1,041
%Δ $1,090.22	-26%	-24%	-22%	-20%	-17%	-15%	-13%	-11%	-9%	-7%	-5%
%Δ $993.57	-19%	-16%	-14%	-12%	-9%	-7%	-5%	-2%	0%	2%	5%
140 MINUTES INTRA-OP	$825	$850	$875	$901	$926	$951	$976	$1,001	$1,026	$1,051	$1,077
%Δ $1,090.22	-24%	-22%	-20%	-17%	-15%	-13%	-10%	-8%	-6%	-4%	-1%
%Δ $993.57	-17%	-14%	-12%	-9%	-7%	-4%	-2%	1%	3%	6%	8%
150 MINUTES INTRA-OP	$843	$870	$897	$924	$951	$978	$1,005	$1,032	$1,059	$1,086	$1,112
%Δ $1,090.22	-23%	-20%	-18%	-15%	-13%	-10%	-8%	-5%	-3%	0%	2%
%Δ $993.57	-15%	-12%	-10%	-7%	-4%	-2%	1%	4%	7%	9%	12%

SCENARIO #6

WHAT DOES IT TAKE TO BREAK EVEN?

MCDA PROPRIETARY REPORT

It appears unlikely that 645X1 will be paid as much as $1000. Over a wide spectrum of scenarios considered, we estimate a (mathematical) expected value for the rate of $829.28 and are just 2.4% confident that the rate would exceed $1000. A rate of $1500 was fully beyond the bounds of our scenarios and probability model and would require extraordinary differences between the data CMS relies on to set the rate and the most aggressive policy drivers our research suggested were possible.



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