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Date: July 5, 2021

Subject: Technical analysis of potential rate proposals for CPT® code 645X1, identifying hypoglossal vs. vagal nerve stimulator implantation service 64568[1]

We are anticipating the Centers for Medicare and Medicaid Services (CMS) to propose reimbursement in the PFS 2022 proposed rule for a new CPT® code relevant to Inspire Medical, currently listed as 645X1 by the American Medical Association (AMA). There is significant speculation and uncertainty around what the proposed rates will be; Inspire Medical has expressed confidence that the rates will likely exceed $1,000 per service and may be as high as $1,500.

Muller Consulting & Data Analytics (MCDA) has been working with Washington Analysis to evaluate considerations and possible proposals that CMS may propose when the rule is released in July. This memo is organized as follows:

1. Key Findings
2. Underlying modeling assumptions
3. PFS Rate Simulations for Full Range of Scenarios
4. Expected Values of Rates and Confidence Levels in Rates Exceeding $1000
5. Input Assumptions Necessary for Rates to Exceed $1000
6. Conclusions
7. Questions and Comments

Key Findings

- Using the information available to us from Washington Analysis's and MCDA's research, including Inspire Medical's own guidance about the procedure to patients, 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.

- In order for 645X1 to attain a rate over $1,000 per service, it appears necessary that intensity, time, or both must be increased very significantly above those for 64568, which is likely to be the key reference code from which the value of 645X1 is derived. However, this degree of intensity and time increase appears unlikely, based on what we know about the code from the AMA, physicians interviewed by Washington Analysis, Inspire's recent FDA approval, and academic literature.

    - These sources appear to suggest an intra-service physician time of between 90 and 150 minutes and an intensity 30%-60% higher than that for the 64568 / 64569 vagus nerve

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procedure(s), which would not achieve $1,000 under reasonable assumptions and other parameters driving the code's reimbursement.

  - Inspire's own guidance to patients is that the procedure (the intra-service portion of the physician work) takes "about 2 hours," suggesting significant increases in physician time over 120 minutes are probably unlikely.

  - Therefore, for CMS to propose a rate over $1,000, it appears the agency would need to receive – *and accept* – recommendations from the RUC that indicate a far more time consuming and intense service than implied by the sources listed above, and to not be aware of Inspire's own guidance to patients about the duration of the procedure.

- In order for 645X1 to attain a rate of $1500, 645X1 would need to be based on extremely aggressive assumptions about both the intra-service procedure duration and the prolonged intensity over that duration.

  - Specifically, if CMS assumed the intra-service portion took a full hour longer than Inspire tells patients it does, then they would still need to increase the intensity through the procedure to 375% of what we understand is currently assumed for 64568, or to 254% of what is assumed for 64569.

Underlying Modeling Assumptions

What CMS will ultimately propose around 645X1 turns on several drivers, a number of which we classify as "highly uncertain" and others as "somewhat uncertain." To perform the modeling, we, therefore made assumptions around the "somewhat uncertain" drivers of reimbursement and simulated a wide range of plausible scenarios for the "highly uncertain" drivers. Once we had simulated the broad range of scenarios, we then converted the analyses based on our background research into the service and understanding of CMS's reimbursement tendencies into subjective probabilities on each of the remaining dimensions – the "highly uncertain" reimbursement drivers.

The drivers we considered relatively predictable, and therefore treated as fixed assumptions in our modeling, were:

- Pre-service and post-service physician work time, for which we assumed 81 minutes combined. In the 64568 service, CMS assumes the physician works for 51 minutes before the service and 30 minutes after the service. The pre-service activities include reviewing and evaluating the patient, pre-surgical positioning, and scrubbing & dressing for the procedure. The post-service activities primarily include evaluating the status of the patient following the procedure. We could not find known arguments for substantially increasing these time assumptions for the hypoglossal service vs. vagus, and even if they were increased nominally (say by 7 minutes to the levels used for the vagus *replacement* procedure under 64569), these activities are assigned such a low intensity (IWPUT) value that their reimbursement effect would be minimal.

- Practice expense (PE) direct costs, for which we mirrored the 64568 assumption of $68.48. In general, facility-based procedures receive only minimal direct inputs, as the hospital provides almost all of the clinical labor, medical supplies, and medical equipment needed for the service. Consistent with this, in 64568, non-physician clinical labor is almost entirely confined to pre- and post-service costs (preparing the patient for the procedure and post-operative follow-up activities), with just 12 minutes during the intra-service period itself (what we think of as "doing the

operation"). The medical supplies involve two low-cost kits, one of which appears to be for the operation itself and one of which is for the post-operative activities. All of the medical equipment appears to be for post-operative activities. Given that these costs seemed unlikely to vary if the intra-service activities were extended or assumed to be more intense and that any additional intra-service direct costs were insignificant, we held these fixed.

- Post-operative evaluation & management (E&M) work RVUs. The vagus code 64568, and likely the hypoglossal code 645X1, assume what CMS terms a "90-day global period," in which certain services related to the initial procedure are not paid. Instead, the code's direct inputs incorporate costs the practice would incur in the 90-day global period (as noted in the direct costs assumption we mentioned above) and the work RVUs incorporated into post-operative E&M visits. 64568 assumes four post-op E&M visits, totaling 3.98 work RVUs. However, because CMS has since updated its E&M work RVU values in 2021 to 4.64, we assumed 645X1's work RVU would incorporate 4.64 work RVUs for the post-op E&M visits.

- The mix of specialties that will bill 645X1. When CMS proposes a rate for 645X1, its methodology requires an assumption about the mix of specialties that will bill the code. This assumption affects the *indirect* practice expense RVUs allocated to the service. For the vagus nerve code 64568, this is typically performed by a range of specialties, including around 46% otolaryngology. For the add-on code 0466T, almost all (over 95%) in 2019 and 2020 were performed by otolaryngologists, according to Medicare claims data. However, 645X1 is essentially a successor to the code combination 64568 + 0466T when billed for the same patient on the same day. In that case, according to the 2019 and 2020 claims data, 100% of combined services were billed by otolaryngologists. Therefore, it is likely that CMS will assume 100% otolaryngology for the code, and even if they choose another method (such as blending the overall 64568 specialty mix with the overall 0466T specialty mix), the code's reimbursement would almost certainly be based on 100% otolaryngology once the code is reimbursed using actual billed 645X1 services (starting 2024). We, therefore, assumed 100% otolaryngology, which we note had the effect of modestly decreasing the indirect practice expense RVU below that for 64568.

The drivers we considered "highly uncertain" and incorporated into individual scenarios are:

- Whether CMS will consider 64568 or 64569's work RVU to be the "base case" for 645X1. We estimated that 64568 was valued using an intra-service intensity of 0.0357 (deduced by subtracting the post-operative E&M work RVUs and the contribution of the pre- and immediate post-op physician time). According to the AMA, 64569 was valued using an intra-service IWPUT of 0.0439.

- The previous assumption is important because some feedback we received was that work time might increase by around 30%-60% from where it is currently, and it is unclear whether that baseline was the initial implantation procedure or the more intense and time-consuming replacement procedure. Noting that 64569's IWPUT of 0.0439 is already ~23% greater than 64568's 0.0357, we, therefore, simulated the full range of combinations from 100% of the baseline procedure's IWPUT up to 200% of baseline.

- The number of intra-service physician minutes. We understand 645X1 is likely to assume more intra-service minutes than "the current procedure" and that if the sources we are aware of are representative of CMS's thinking, then the likely range is probably 120-150 minutes (vs. 90 for 64568 and 120 for 64569). Additionally, Inspire's patient FAQ includes a video titled "What is involved in the Inspire procedure and recovery," in which Inspire advises patients: "*[Inspire is] a*

same-day outpatient procedure that takes about 2 hours. The procedure consists of 2 or 3 small incisions. One incision will be made in the upper chest, where a small device and breathing sensor are placed. Another incision will be made under your chin. That's where the nerve that controls your tongue is located, so a small cuff is placed on the nerve to tell your tongue to move out of the way. A third incision is sometimes used to place the breathing sensor in your lower chest."[2] We, therefore, simulated the full range from the 64568 status quo of 90 minutes up to the 150-minute upper bound from our sources; this matches Inspire's patient guidance of "about 2 hours," plus or minus 30 minutes.

- Whether the malpractice RVU is based on 64568 (2.22) or 64569 (3.29). It is unclear which of these would be used – or somewhere in the middle – however, we could see no reason that the malpractice RVU would be materially higher or lower than this range.

Based on the background research conducted by Washington Analysis and MCDA – and our impressions of CMS's responses to various levels of aggressiveness about proposals it receives from the RUC and stakeholders – we specified subjective probabilities for each of the "highly uncertain" reimbursement drivers. As with any such expert-judgment exercise about the probabilities of outcomes, these are highly subjective, and others could certainly disagree with both our ultimate outcome conclusions as well as the *range* of potential outcomes. The subjective probabilities we assumed are as follows.

Whether 64568 or 64569 is the baseline. (Table 1(a).) It seems more likely that 645X1 will be built relative to the "initial implantation" vagus code 64568, since that is its equivalent between the two code groups. However, given the discussions about increased time and intensity, it seems possible that the "replacement" code 64569 could be used instead. It is additionally unclear to us whether physicians, when talking about "higher intensity," are referring to the initial fitting procedure, the replacement procedure, or some mental mixture of both.

Table 1(a). Subjective probability assumption for whether 64568 or 64569 is 645X1's primary reference code

Baseline Code	Subjective Probability Assumed
64568	67%
64569	33%

The increase in intra-service intensity (IWPUT) vs. baseline. It appears that intensity will increase relative to the "baseline" code and, per our research, the range of +30% to +60% appears most probable. However, as the AMA has noted the apparently quite low IWPUT value for 64569, we recognize that it is possible the intensity is increased more substantially than 30%-60% relative to the baseline code; we have specified probabilities up to 200%, quickly decaying down above a 60% increase. We note that CMS clinical advisors attend the RUC meetings and then perform their own reviews of facts behind RUC and other stakeholder recommendations, and so we think it most likely that CMS is relying on similar information to us for their independent review.

Table 1(b). Subjective probability assumptions about how much higher 645X1's IWPUT will be relative to the base code

[2] See https://www.inspiresleep.com/faq/.

Increase from Baseline	IWPUT (if 64568 is baseline)	IWPUT (if 64569 is baseline)	Subjective Probability Assumed
100%	0.0439	0.0439	6%
110%	0.0483	0.0483	7%
120%	0.0527	0.0527	11%
130%	0.0571	0.0571	15%
140%	0.0615	0.0615	17%
150%	0.0659	0.0659	18%
160%	0.0702	0.0702	13%
170%	0.0746	0.0746	7%
180%	0.0790	0.0790	4%
190%	0.0834	0.0834	2%
200%	0.0878	0.0878	1%
			100%

The number of intra-service minutes assumed. Our research suggests the intra-service minutes a physician takes to perform the service falls somewhere above 90 and probably no more than 150. With Inspire Medical itself having noted that 90% of services are performed in less than 120 minutes, we did not extend the minutes assumption beyond 150 (e.g., to 180, fully doubling the minutes from 64568). Similar to the IWPUT assumption, we note that CMS's clinical advisors (who attend RUC meetings and then perform their own independent evaluations of what the RUC might recommend) would likely be relying on similar information as we used in developing these probabilities.

Table 1(c). Subjective probability assumptions about the number of intra-service physician minutes for 645X1

Intra-Service Minutes	Relative to 64568	Relative to 64569	Subjective Probability Assumed
90	100%	75%	8%
100	111%	83%	12%
110	122%	92%	23%
120	133%	100%	23%
130	144%	108%	15%
140	156%	117%	12%
150	167%	125%	8%
		Total:	100%

Whether the malpractice (MP) RVU is equal to 64568's or 64569's. While this factor has a less significant impact on the final rate, it seems more likely that malpractice costs would be simply based on 64568's physician liability vignette. However, we give a modest probability that it is at the higher 64569 MP RVU level of 3.29.

Table 1(d). Subjective probability assumptions about whether 645X1's malpractice RVU will be similar to 64568's or 64569's

Baseline Code	MP RVU	Subjective Probability Assumed
64568	2.22	70%
64569	3.29	30%
		100%

PFS Rate Simulations for Full Range of Scenarios

Using the above assumptions and variables, we formed four sets of simulations, one for each combination of base code assumptions (64568: IWPUT 0.0357; 64569: IWPUT 0.0439) and malpractice RVUs (2.22, 3.29). For each set, we then simulated the total PFS rate using the 2021 PFS rate-setting methodology and data for the range of increases to the IWPUT (from the baseline) and the minutes of intra-service physician time. Simulations were performed on MCDA's full replication of CMS's PFS rate-setting methodology.

In Tables 2(a-d) below, the intra-service physician minutes increases along rows, and the intra-service intensity increases along columns. The dollar values in cells are the simulated national payment rates (as they would have been in 2021), and colors proceed from red to green as rates increase. In the bottom-right of each table, the rates over $1000 are delimited by a border.

The minimum simulated rate across the Tables is $653.64, holding the intra-service time at 90 minutes, the intra-service intensity equal to 64568's at 0.0357, and paying 2.22 in malpractice RVUs. The maximum simulated rate across the tables is $1192.08, increasing the intra-service time to 30 minutes beyond Inspire's guidance to patients and fully doubling the intensity beyond 64569's 0.0439 IWPUT, and paying 3.29 malpractice RVUs per service.

Table 2(a). Assume baseline intensity is 64568's intra-service IWPUT of 0.0357 and malpractice RVU is 2.22

Intra-service IWPUT assumption:											
Increase	**Baseline**	**+10%**	**+20%**	**+30%**	**+40%**	**+50%**	**+60%**	**+70%**	**+80%**	**+90%**	**+100%**
Value	0.0357	0.0392	0.0428	0.0464	0.0499	0.0535	0.0571	0.0606	0.0642	0.0677	0.0713
Intra-service time assumption:											
90 minutes	$ 653.64	$ 669.78	$ 685.93	$ 702.07	$ 718.22	$ 734.36	$ 750.51	$ 766.65	$ 782.80	$ 798.94	$ 815.09
100 minutes	$ 671.57	$ 689.51	$ 707.45	$ 725.39	$ 743.33	$ 761.27	$ 779.21	$ 797.15	$ 815.09	$ 833.02	$ 850.96
110 minutes	$ 689.51	$ 709.25	$ 728.98	$ 748.71	$ 768.44	$ 788.18	$ 807.91	$ 827.64	$ 847.38	$ 867.11	$ 886.84
120 minutes	$ 707.45	$ 728.98	$ 750.51	$ 772.03	$ 793.56	$ 815.09	$ 836.61	$ 858.14	$ 879.67	$ 901.19	$ 922.72
130 minutes	$ 725.39	$ 748.71	$ 772.03	$ 795.35	$ 818.67	$ 841.99	$ 865.31	$ 888.64	$ 911.96	$ 935.28	$ 958.60
140 minutes	$ 743.33	$ 768.44	$ 793.56	$ 818.67	$ 843.79	$ 868.90	$ 894.02	$ 919.13	$ 944.25	$ 969.36	$ 994.47
150 minutes	$ 761.27	$ 788.18	$ 815.09	$ 841.99	$ 868.90	$ 895.81	$ 922.72	$ 949.63	$ 976.54	$ 1,003.44	$ 1,030.35

Table 2(b). Assume baseline intensity is 64569's intra-service IWPUT of 0.0439 and malpractice RVU is 2.22

Intra-service IWPUT assumption:											
Increase	**Baseline**	**+10%**	**+20%**	**+30%**	**+40%**	**+50%**	**+60%**	**+70%**	**+80%**	**+90%**	**+100%**
Value	0.0439	0.0483	0.0527	0.0571	0.0615	0.0659	0.0702	0.0746	0.0790	0.0834	0.0878
Intra-service time assumption:											
90 minutes	$ 690.95	$ 710.83	$ 730.71	$ 750.58	$ 770.46	$ 790.34	$ 810.22	$ 830.09	$ 849.97	$ 869.85	$ 889.72
100 minutes	$ 713.04	$ 735.12	$ 757.21	$ 779.30	$ 801.38	$ 823.47	$ 845.55	$ 867.64	$ 889.72	$ 911.81	$ 933.89
110 minutes	$ 735.12	$ 759.42	$ 783.71	$ 808.01	$ 832.30	$ 856.60	$ 880.89	$ 905.18	$ 929.48	$ 953.77	$ 978.07
120 minutes	$ 757.21	$ 783.71	$ 810.22	$ 836.72	$ 863.22	$ 889.72	$ 916.23	$ 942.73	$ 969.23	$ 995.73	$ 1,022.24
130 minutes	$ 779.30	$ 808.01	$ 836.72	$ 865.43	$ 894.14	$ 922.85	$ 951.56	$ 980.27	$1,008.98	$ 1,037.70	$ 1,066.41
140 minutes	$ 801.38	$ 832.30	$ 863.22	$ 894.14	$ 925.06	$ 955.98	$ 986.90	$1,017.82	$1,048.74	$ 1,079.66	$ 1,110.58
150 minutes	$ 823.47	$ 856.60	$ 889.72	$ 922.85	$ 955.98	$ 989.11	$1,022.24	$1,055.36	$1,088.49	$ 1,121.62	$ 1,154.75

Table 2I. Assume baseline intensity is 64568's intra-service IWPUT of 0.0357 and malpractice RVU is 3.29

Intra-service IWPUT assumption:											
Increase	**Baseline**	**+10%**	**+20%**	**+30%**	**+40%**	**+50%**	**+60%**	**+70%**	**+80%**	**+90%**	**+100%**
Value	0.0357	0.0392	0.0428	0.0464	0.0499	0.0535	0.0571	0.0606	0.0642	0.0677	0.0713
Intra-service time assumption:											
90 minutes	$ 690.97	$ 707.11	$ 723.26	$ 739.40	$ 755.55	$ 771.69	$ 787.84	$ 803.98	$ 820.13	$ 836.27	$ 852.42
100 minutes	$ 708.91	$ 726.84	$ 744.78	$ 762.72	$ 780.66	$ 798.60	$ 816.54	$ 834.48	$ 852.42	$ 870.36	$ 888.29
110 minutes	$ 726.84	$ 746.58	$ 766.31	$ 786.04	$ 805.78	$ 825.51	$ 845.24	$ 864.97	$ 884.71	$ 904.44	$ 924.17
120 minutes	$ 744.78	$ 766.31	$ 787.84	$ 809.36	$ 830.89	$ 852.42	$ 873.94	$ 895.47	$ 917.00	$ 938.52	$ 960.05
130 minutes	$ 762.72	$ 786.04	$ 809.36	$ 832.68	$ 856.00	$ 879.33	$ 902.65	$ 925.97	$ 949.29	$ 972.61	$ 995.93
140 minutes	$ 780.66	$ 805.78	$ 830.89	$ 856.00	$ 881.12	$ 906.23	$ 931.35	$ 956.46	$ 981.58	$ 1,006.69	$ 1,031.81
150 minutes	$ 798.60	$ 825.51	$ 852.42	$ 879.33	$ 906.23	$ 933.14	$ 960.05	$ 986.96	$1,013.87	$ 1,040.78	$ 1,067.68

Table 2(d). Assume baseline intensity is 64569's intra-service IWPUT of 0.0439 and malpractice RVU is 3.29

Intra-service IWPUT assumption:											
Increase	**Baseline**	**+10%**	**+20%**	**+30%**	**+40%**	**+50%**	**+60%**	**+70%**	**+80%**	**+90%**	**+100%**
Value	0.0439	0.0483	0.0527	0.0571	0.0615	0.0659	0.0702	0.0746	0.0790	0.0834	0.0878
Intra-service time assumption:											
90 minutes	$ 728.29	$ 748.16	$ 768.04	$ 787.92	$ 807.79	$ 827.67	$ 847.55	$ 867.42	$ 887.30	$ 907.18	$ 927.05
100 minutes	$ 750.37	$ 772.46	$ 794.54	$ 816.63	$ 838.71	$ 860.80	$ 882.88	$ 904.97	$ 927.05	$ 949.14	$ 971.23
110 minutes	$ 772.46	$ 796.75	$ 821.04	$ 845.34	$ 869.63	$ 893.93	$ 918.22	$ 942.51	$ 966.81	$ 991.10	$ 1,015.40
120 minutes	$ 794.54	$ 821.04	$ 847.55	$ 874.05	$ 900.55	$ 927.05	$ 953.56	$ 980.06	$1,006.56	$ 1,033.07	$ 1,059.57
130 minutes	$ 816.63	$ 845.34	$ 874.05	$ 902.76	$ 931.47	$ 960.18	$ 988.89	$1,017.61	$1,046.32	$ 1,075.03	$ 1,103.74
140 minutes	$ 838.71	$ 869.63	$ 900.55	$ 931.47	$ 962.39	$ 993.31	$1,024.23	$1,055.15	$1,086.07	$ 1,116.99	$ 1,147.91
150 minutes	$ 860.80	$ 893.93	$ 927.05	$ 960.18	$ 993.31	$1,026.44	$1,059.57	$1,092.70	$1,125.82	$ 1,158.95	$ 1,192.08

Expected Values of Rates and Confidence Levels that Rates Exceeding $1000

The simulated total rates and the underlying subjective probability assumptions listed above allow us to calculate the (mathematical) expected values and the confidence levels that the rates would exceed $1,000. In this section, we summarize these statistics. Before we present the statistics, readers should be clear about what these statistics mean in the context of our analysis:

> The expected values (or confidence levels that rates exceed $1000) represent the average total rates (or confidence levels) across the range of possibilities under PFS 2021 final rule methods and data; **and:**
>
> - the fixed assumptions listed above hold,
> - the determinants we allowed to vary between scenarios stay within the ranges we considered, and
> - the subjective probabilities assigned to the range of possibilities are generally appropriate.
>
> That is, the expected values and confidence levels reflect our subjective judgment about what is possible and the likelihoods of various policy configurations occurring in the PFS 2022 proposed rule, which in turn were informed by the evidence available to us (the Washington Analysis and MCDA interviews and research) and our familiarity with the CMS rate-setting process.

For this exercise, we treat the four factors varying rates – the baseline code for IWPUT calculations, the percentage increase in IWPUT, the intra-service physician minutes, and the malpractice RVU – as statistically independent. The "joint subjective probability" of each particular scenario is, therefore, the product of the four factors' probabilities corresponding to that scenario.

Finally, however, we note that, in reality, CMS will also consider the face validity of the overall resulting payment rate (particularly for the work RVU) relative to the current vagus nerve procedure 64568, in which case it is possible that CMS could essentially avoid some of the higher-paying scenarios (for example, if they are greater than the current 64568+0466T code combination, paid at roughly $993). In that case, the expected value of rates would decrease slightly, and the probabilities that the rate exceeds $1000 would decrease, potentially to zero.

With these qualifications, Table 3(a) presents the expected values of rates corresponding to Tables 2(a-d) and under the subjective probability assignments in Tables 1(a-d); and Table 3(b) presents the estimated probability that the rates would exceed $1000.

Table 3(a). Expected values of simulated PFS rates under assumed subjective probabilities

			MP RVU Assumption		
	Assumption		2.22	3.29	
		Subjective Probability	70%	30%	
Baseline IWPUT Assumption	64568	67%	$ 794.77	$ 832.10	$ 805.97
	64569	33%	$ 864.71	$ 902.04	$ 875.91
			$ 818.08	$ 855.41	$ 829.28

Table 3(a) shows that, over all scenarios and with the qualifications emphasized above, *our* expected value of rates is $829.28. If 64568 is used as the baseline case for IWPUT, *our* expected value of rates is $805.97, but if 64569 were used instead, that increases to $875.91. Similarly, assuming a malpractice RVU of 2.22 (equal to that of 64568), our expected value of rates is $881.08, and assuming 3.29 (equal to that of 64569), that number increases to $855.41. Under what we believe is the most likely configuration of baseline IWPUT and malpractice RVU, our expected value of rates (corresponding to Table 2(a)) is $794.77. Under the most optimistic configuration of baseline IWPUT and malpractice RVU, our expected value of rates (corresponding to Table 4(d)) is $902.04.

Table 3(b). Confidence that PFS rates will exceed $1000

			MP RVU Assumption		
	Assumption		2.22	3.29	
		Subjective Probability	70%	30%	
Baseline IWPUT Assumption	64568	67%	0.2%	0.8%	0.4%
	64569	33%	4.8%	10.3%	6.5%
			1.8%	4.0%	2.4%

Table 3(b) shows that, over all scenarios, our assumptions and subjective probabilities translate into a *2.4% confidence that the PFS rate for 645X1 will exceed $1000*. Under what we believe is the most likely configuration of baseline IWPUT and malpractice RVU, we are just 0.2% confident that the rate will exceed $1000. Under the most optimistic configuration of baseline IWPUT and malpractice RVU, we are 10.3% confident that the rate will exceed $1000.

Obviously, the estimates presented in Tables 3(a) and 3(b) are in stark contrast with Inspire Medical's stated confidence that 645X1's rate will exceed $1000 and could be as high as $1500. Similarly, it is certainly possible that the RUC and CMS have reviewed information that suggests a much higher rate than our modeling implies. However, that would require the information presented to the RUC and CMS to reflect higher intensity and physician time than we had reviewed – including physician interviews, Inspire's statements around their recent FDA approval, previous RUC materials, and academic literature noting the duration of the procedure. See Washington Analysis's main note for more details on the sources that informed our priors.

Input Assumptions Necessary for Rates to Exceed $1000

Given the limited information set available before CMS releases their 2022 PFS proposed rule (after which the RUC meeting minutes and certain related materials will also be released), we finally present a rate analysis profiling the intra-service physician minutes and intensity (IWPUT) required to attain rates of $1000, $1250 and $1500. Figure 1(a) presents the solutions when the malpractice RVU is 2.22, and Figure 1(b) presents the solutions when the malpractice RVU is 3.29. In these level set plots, we have extended the possible physician minutes out to 180 (a full doubling of the physician time from 64568), and present, for reference, three benchmark levels for IWPUT: our estimate of the current IWPUT for 64568, 0.0357; the publicly known IWPUT for 64569, 0.0439; and the IWPUT threshold CMS uses for considering a code's intensity to be an outlier, 0.1400. Readers anticipating rates over $1000 may use these Figures to fact check their expectations against their beliefs about the ultimate determinants of the outcome: intra-service physician time and intensity.

In Figure 1(a), assuming malpractice RVU is 2.22, if a full additional hour of physician time were added beyond that assumed in 64568 – increasing time from 90 to 150 minutes – then:

- A rate of $1000 would require intensity to increase to 0.0673 (189% of 64568's IWPUT and 153% of 64569's IWPUT);
- A rate of $1250 would require intensity to increase to 0.1004 (282% of 64568's IWPUT and 229% of 64569's)
- A rate of $1500 would require intensity to increase to 0.1334 (375% of 64568's IWPUT and 304% of 64569's), almost up to CMS's definition of IWPUT being an outlier.

To interpret, if the reader was expecting a rate of $1500, and thought it was reasonable that the entire hypoglossal implantation procedure incurred 2.5 hours of work, then that entire 2.5 hours would need to average close to an outlier rate of physician work intensity.

If instead, intra-service physician time were set above the upper bound of the information we reviewed in our research, to fully double the 64568 physician time to 180 minutes, then:

- A rate of $1000 would require intensity to increase to 0.0561 (157% of 64568's IWPUT and 128% of 64569's IWPUT);
- A rate of $1250 would require intensity to increase to 0.0837 (235% of 64568's IWPUT and 229% of 64569's)
- A rate of $1500 would require intensity to increase to 0.1113 (375% of 64568's IWPUT and 254% of 64569's).

At the other end of the spectrum, if intra-service physician time were set to 120 minutes – i.e., the approximate duration Inspire instructs patients the procedure takes—then:

- A rate of $1000 would require intensity to increase to 0.0841 (236% of 64568's IWPUT and 192% of 64569's IWPUT);
- A rate of $1250 would require intensity to increase to 0.1255 (352% of 64568's IWPUT and 286% of 64569's)
- A rate of $1500 would require intensity to increase to 0.1669 (468% of 64568's IWPUT and 380% of 64569's, and 20% higher than the CMS IWPUT outlier threshold).

These observations suggest that, for Inspire Medical's confidence about rates exceeding $1000 and potentially being as high as $1500, they must receive both a generous time assumption and a significant increase in intensity. To attain $1500, if CMS adopts Inspire's own guidance to patients about the procedure duration ("about 2 hours," or 120 minutes), the IWPUT level would need to be higher than the CMS outlier threshold. This is by no means impossible, however, at that point, the magnitude of the IWPUT would raise questions about the survivability of the proposal as part of the agency's final regulation this fall. On the other hand, if the IWPUT is only raised by a modestly aggressive amount (say to 157% of 64568 or 128% of 64569), then attaining a high reimbursement would require CMS to assume the procedure takes far longer than Inspire instructs patients it takes.

Figure 1(a). Intra-Service IWPUT and physician time to attain PFS rates of $1000-1500 under malpractice RVU of 2.22

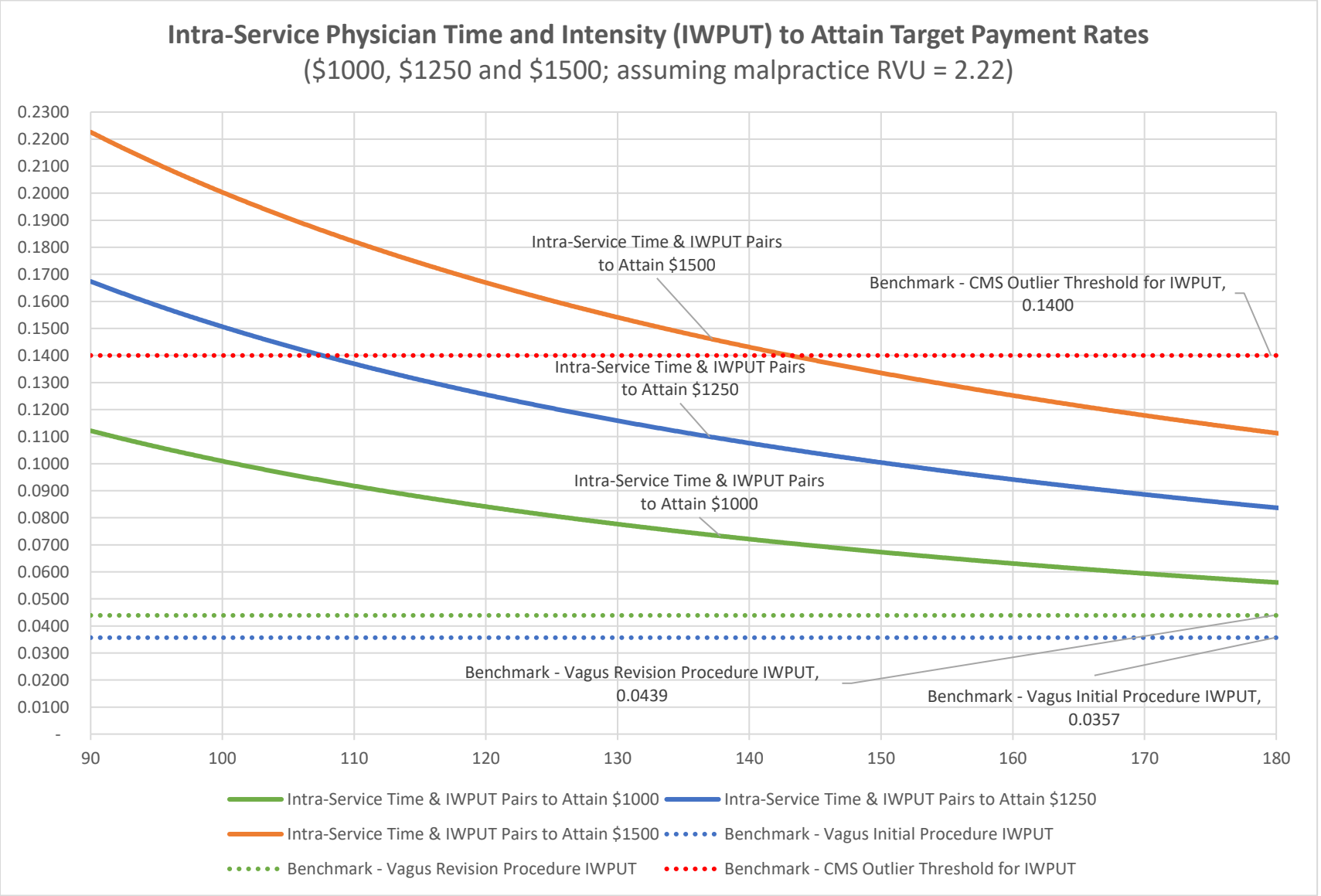
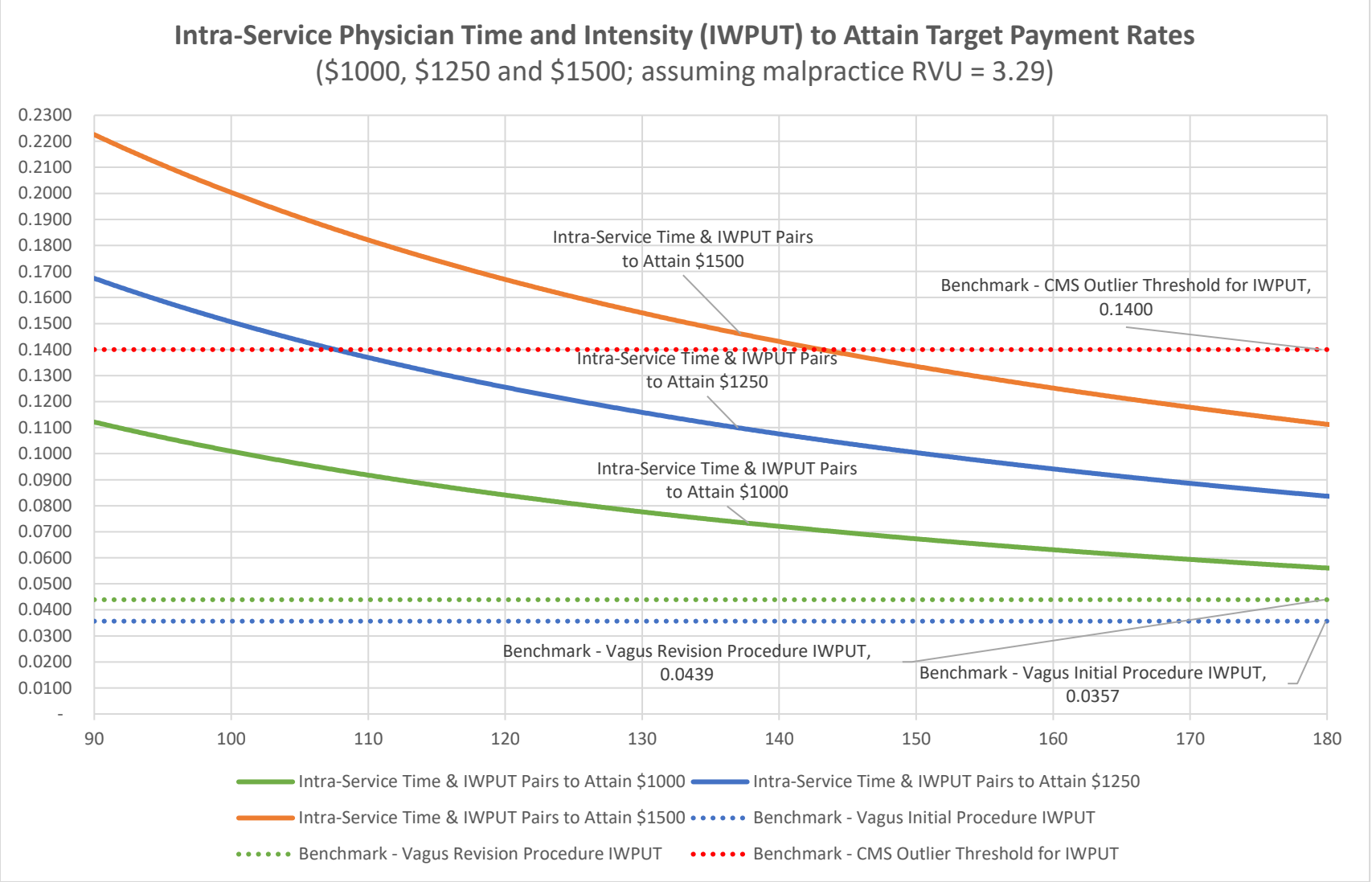


Figure 1(b). Intra-Service IWPUT and physician time to attain PFS rates of $1000-1500 under malpractice RVU of 3.29



Conclusions

Ultimately, 645X1's likely proposed rate turns on what the RUC has received from stakeholders, what the RUC made of that information, what CMS received from the RUC (and potentially Inspire Medical), and what CMS is willing to pay in the context of existing procedures (e.g., 64568), as well as their independent review of all of the materials. Until the RUC materials and CMS's commentary on its proposal are published, any attempt to predict what CMS will do is subject to a heavy information asymmetry.

However, we do know the mechanics of the physician fee schedule, Inspire's own guidance to patients about how long the procedure takes, academic literature on the same, and the known intensities for the reference procedures – the initial implantation of the vagus nerve stimulation, 64568, and the more time consuming and intense revision of the same, 64569. These pieces of information allowed us to specify and simulate payment rates across the likely spectrum of possibilities; additionally, these factors allowed us to specify subjective probabilities for each configuration of factors determining the ultimate payment rate.

Relying on the available information, it appears quite unlikely that 645X1 will receive a payment rate exceeding $1000, and very unlikely it will receive a payment rate as high as $1500. (We estimated an expected value of rates of $829.28 across our scenarios and using our subjective probabilities of each scenario occurring.) For either of those outcomes to occur, it appears CMS will need to either be in a particularly generous mood or relying on information that, essentially, completely disagrees with our sources (including Inspire's own guidance to patients); or that CMS abandons considering relativity between the vagus and hypoglossal nerve stimulator implant procedure's work intensities.

While it is certainly possible that CMS relies on data in conflict with our sources, or that the agency fully quarantines its thinking about the hypoglossal procedure from the vagus nerve procedure, doing so would raise a reasonable and significant question about the *validity* of such a rate proposal, which would pose short-term risks to that proposal, and long-term risks when the code's payment rate is reviewed in the future. That is, even if CMS were to propose rates of $1000 or even $1500 in the PSF 2022 proposed rule, it is unclear whether any such proposal would survive to the final rule, and then it is unclear whether it would survive CMS and the RUC's longer-term ongoing reviews of potentially misvalued services.

Questions and Comments

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