

Neuromodulation Payment Policy (NPP) Coalition

REQUEST FOR A LEVEL 6 NEUROSTIMULATOR AND RELATED
SERVICES APC FOR CY 2026

MAY 13, 2025



Summary of the NPP Coalition's Requests

- **Create a new Level 6 Neurostimulator and Related Services (APC 5466) effective January 1, 2026**
 - Multiple stimulation technologies have total GMCs ranging from ~\$44,000-\$52,000, with two of these technologies currently assigned to New Technology APC 1580
 - Creating a new clinical Level 6 APC is consistent with CMS' methodology of comprehensive APCs, utilizing as many claims as possible for rate setting, and averaging similar procedures to provide stable payment levels based on Medicare claims
 - There are sufficient claims to analyze and set an appropriate payment level for a Level 6 APC
- **Include this proposal in the CY 2026 Proposed OPPS Rule to allow for stakeholder input**

Neuromodulation Payment Policy (NPP) Coalition

- The NPP Coalition was created in 2019 and includes companies with stimulation technologies that treat a range of disease states
 - CVRx – Barostim carotid artery stimulation for heart failure
 - ZOLL Respicardia – phrenic nerve stimulation for central sleep apnea
 - MicroTransponder – paired vagus nerve stimulation for stroke therapy
 - SetPoint Medical – investigational neurostimulator for autoimmune conditions
 - LivaNova – VNS therapy for drug resistant epilepsy and treatment resistant depression
- The NPP Coalition has made several requests to CMS to create a new Neurostimulator and Related Services APC based on Medicare reported hospital claims
 - For CY 2021, creation of a Level 5 Neurostimulator APC was requested
 - For CY 2022, 2023 and 2025, creation of a Level 6 APC was requested
 - For CY 2026, we again request a Level 6 APC be created

Summary of Recent OPPS Rulemaking Decisions

- **HOP Panel (August 26, 2024) recommended the creation of a Level 6 APC**
- **Significant number of public comments on the Proposed Rule supported creation of a Level 6 APC**
 - Two comments supported maintaining the current five-level structure
- **5-level APC structure maintained in CY 2025 Final Rule**
 - *“While we understand the concerns and issues commenters have raised, we believe that the 5 level APC structure for the series continues to remain appropriate in grouping together procedures with similar cost and clinical characteristics”*
 - No additional details provided by CMS on their rationale for maintaining the 5-level structure
- **In 2023 and 2024 rulemaking** CMS assigned Zoll Respicardia’s phrenic nerve stimulator to New Technology APCs 1581 and then 1580 because its average cost of ~\$44,000 was too high for APC 5465 (Level 5)
- **In 2024 rulemaking** CMS assigned CVRx’s heart failure stimulator device to New Technology APC 1580 stating its average cost of \$47,300 was “substantially higher than the payment rate for APC 5465”.

Rationale for a Level 6 APC

Our analysis of the Neurostimulator APC family continues to demonstrate a Level 6 APC is required to stabilize payment for multiple technologies based on hospital reported costs

- Current APC 5465 GMC is heavily weighted by three high-volume codes, which have significant cost differences from the NPP Coalition technologies
- NPP procedures are increasing in volume, but continue to be a very small percentage of the total claims in APC 5465
- The “average out” concept of APCs does not work as designed if NPP technologies are added into APC 5465
- CMS has addressed other clinical APCs that have significantly less volume and smaller differences in GMC than this request

APC 5465 Neurostimulator and Related Procedures

APC	HCPCS	Description	Q1-Q3, 2024 SAF Hospital Outpatient Claims		
			Single Claims	GMC	2025 Rate \$30,474
5465		Level 5 Neurostimulator APC	16,301	\$32,023*	N/A
	63685	Spinal cord stimulator system or IPG	8,587	\$30,678	(\$204)
	64582	Hypoglossal nerve stimulation system	4,687	\$34,368	(\$3,894)
	61886	Dual chamber IPG for DBS	2,628	\$30,930	(\$456)
	64568*	Vagus nerve stimulation system	328	\$44,393	(\$13,919)
	33287	Central sleep apnea IPG replacement	27	\$39,910	(\$9,436)
	6188E	Complexity adjustment	29	\$49,628	(\$19,154)
	0268T	Heart failure IPG replacement	15	\$39,475	(\$9,001)
1580	0266T**	Carotid artery stimulation system	328	\$45,990	(\$15,516)
	33276**	Phrenic nerve stimulation system	112	\$53,849	(\$23,375)

3 procedures represent 96% of total claims in the APC, all of which are +/- 10% of the GMC of the APC, which in turn drives the GMC and payment level for APC 5465

*Cost of C1827 included in 64568

**GMC and Single Claims are based on a SI of "J1"

Single Claims – claims with only 1 procedure reported are used to set rates

GMC – geometric mean cost is used to understand cost and set rates

 Codes for technologies represented by the NPP

A New Level 6 APC Distributes Costs More Evenly Across all Stimulation Technologies

Claims Analysis – Q1-Q3, 2024 SAF Outpatient Claims

APC	Neurostimulator and Related Procedures	Current APC Structure		Proposed APC	
		Single Claims	GMC	Single Claims	GMC
5461	Level 1	4,524	\$3,653	Not modeled as Levels 1 – 4 would not be impacted by creating a Level 6 APC	
5462	Level 2	12,714	\$6,780		
5463	Level 3	1,690	\$13,472		
5464	Level 4	13,108	\$21,778		
5465	Level 5	16,301	\$32,023	15,946	\$31,797
5466	Proposed Level 6 (including 0266T, 33276, 33287 and 64568)	----	----	795	\$46,120

Proposed Level 6 procedures will likely exceed 1,000 cases in full year 2024 demonstrating broad adoption

Analysis: Using Q1-Q3, 2024 SAF outpatient claims, we calculated the impact of creating a new APC

- Reclassified procedures that had a GMC ~\$40,000+ to the proposed Level 6 Neurostimulator and Related Services APC given the disparity from the GMC of APC 5465
- Followed CMS' methodology utilizing the "J1" status indicator for all procedures analyzed, including 0266T and 33276
- GMC of CPT Code 64568 includes cost of C1827 as TPT expires for this device category on December 31, 2025
- Level 5 and Proposed Level 6 Analysis (no additional analysis of Levels 1-4 performed).

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- NPP procedures are increasing in volume, but continue to be a very small percentage of the total claims in APC 5465
- The “average out” concept of APCs does not work as designed if NPP technologies are added into APC 5465
- CMS has addressed other clinical APCs that have significantly less volume and smaller differences in GMC than this request

NPP procedures are increasing in volume, but continue to account for a small percentage of claims in APC 5465 relative to other procedures

- Claims volume is increasing, however, as a percentage of the total claims in APC 5465, they remain less than 5% of APC 5465 claims
 - 2024 claims volume annualized is expected to be greater than 1,000 claims
- The GMC of these procedures has been consistently greater than the GMC of APC 5465

APC / CPT Code	SI	2022 Claims		2023 Claims		1H, 2024 Claims		Q1-Q3, 2024 Claims	
		Singles	GMC	Singles	GMC	Singles	GMC	Singles	GMC
64568	J1	247	\$45,175	270	\$43,799	212	\$44,102	328	\$44,393
0424T/33276	J1	124	\$48,153	109	\$44,858	78	\$51,939	112	\$53,849
0427T/33287	J1	19	\$35,362	12	\$55,534	18	\$40,405	27	\$39,910
0266T	J1	123	\$47,305	286	\$41,359	205	\$43,780	328	\$45,990
Total NPP Claims		513	\$45,968	677	\$43,097	513	\$44,942	795	\$46,120
APC 5465	J1	18,766	\$30,410	19,928	\$30,843	10,836	\$31,832	16,301	\$32,023
NPP as % of APC 5465		2.7%	151.2%	3.4%	139.7%	4.7%	141.2%	4.9%	144.0%

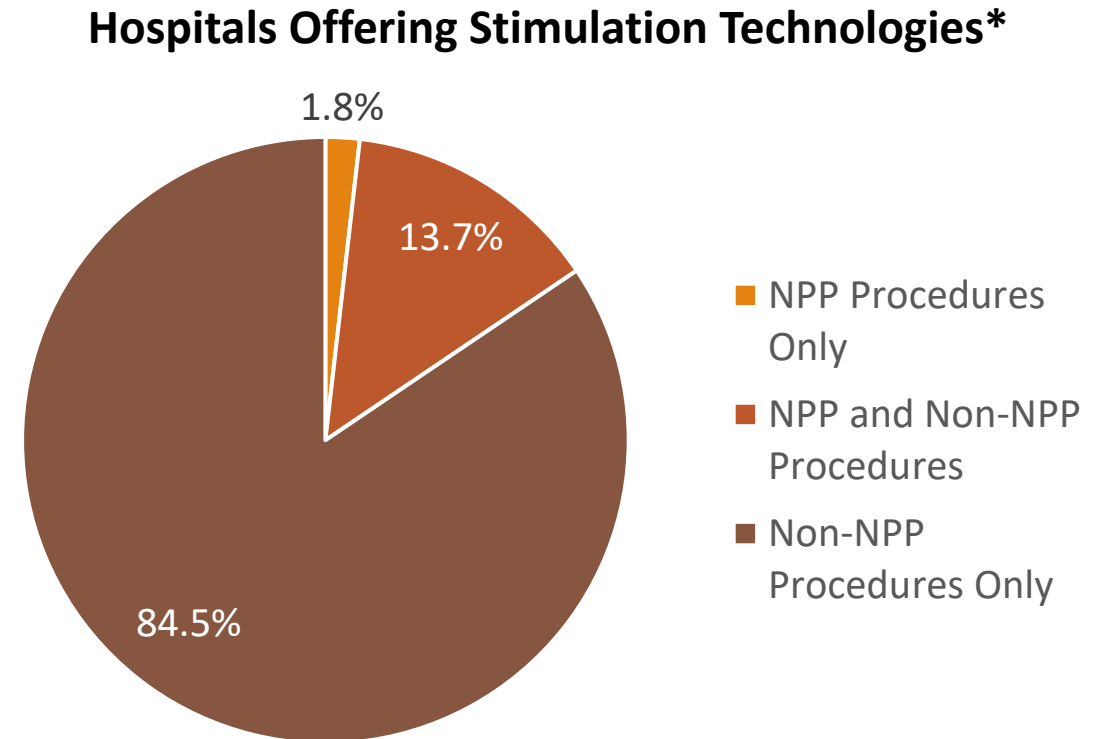
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- Current APC 5465 GMC is heavily weighted by three high-volume codes, which have significant cost differences from the NPP Coalition technologies
- NPP procedures are increasing in volume, but will continue to be a very small percentage of total claims compared to others in APC 5465
- The “average out” concept of APCs will not work as designed if NPP technologies are added to APC 5465
- CMS has addressed other clinical APCs that have significantly less volume and smaller differences in GMC than this request

Financial losses associated with these NPP technologies will not average out across hospitals, disproportionately impacting specialty centers

- NPP technologies are typically only offered by highly-specialized facilities
 - Less than 15% of hospitals offered both NPP and non-NPP technologies
- In addition, medical centers typically evaluate financial impact at the procedure level within a department or service line level
 - NPP technologies range across multiple specialty areas that are managed separately within a hospital



NPP Technologies = 0266T, 0424T, 64568
Non-NPP Technologies = 61866, 63685, 64582

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- CMS created additional levels within clinical APCs to “create a smoother distribution of costs between the different levels based on their resources costs and clinical characteristics”
- For Intraocular Procedures, CMS created an additional level and maintains three APCs (5494-5496) with similar volume and similar GMCs
- We are supportive of how CMS has addressed APCs 5491-5495, and believe a similar approach is required for the Neurostimulator APC family

APC	Intraocular Procedures	CY 2023 (CMS-1772-FC)			CY 2024 (CMS-1786-FC)			CY 2025 (CMS-1809-FC)		
		Singles	# of CPT	GMC	Singles	# of CPT	GMC	Singles	# of CPT	GMC
5491	Level 1	319,846	55	\$2,221	290,825	55	\$2,281	283,337	55	\$2,308
5492	Level 2	63,040	33	\$4,109	47,106	25	\$4,016	44,148	25	\$4,072
5493	Level 3	1,070	7	\$7,422	11,583	17	\$5,169	14,714	14	\$5,222
5494	Level 4	54	1	\$10,747	50	1	\$13,410	88	1	\$13,785
5495	Level 5	18	4	\$13,207	88	1	\$7,523	62	1	\$9,770
5496	Level 6	----	----	----	26	4	\$11,673	29	4	\$10,548

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- **Include this proposal in the CY 2026 Proposed OPPS rule to allow for stakeholder input along with additional details on CMS' rationale**

Thank You

APPENDIX – Technology Overviews

HCPCS Code Definitions of Primary Implant Procedures

Code	Description
0266T	Implantation or replacement of carotid sinus baroreflex activation device; total system (includes generator placement, unilateral or bilateral lead placement, intra-operative interrogation, programming, and repositioning, when performed)
0908T	Open implantation of integrated neurostimulation system, vagus nerve, including analysis and programming, when performed
33276	Insertion of phrenic nerve stimulator system (pulse generator and stimulating lead[s]), including vessel catheterization, all imaging guidance, and pulse generator initial analysis with diagnostic mode activation, when performed
64568	Open implantation of cranial nerve (eg, vagus nerve) neurostimulator electrode array and pulse generator
64582	Open implantation of hypoglossal nerve neurostimulator array, pulse generator, and distal respiratory sensor electrode or electrode array
C1767	Generator, neurostimulator (implantable), nonrechargeable
C1823	Generator, neurostimulator (implantable), nonrechargeable, with transvenous sensing and stimulation leads
C1825	Generator, neurostimulator (implantable), nonrechargeable with carotid sinus baroreceptor stimulation lead(s)
C1827	Generator, neurostimulator (implantable), nonrechargeable, with implantable stimulation lead and external paired stimulation controller

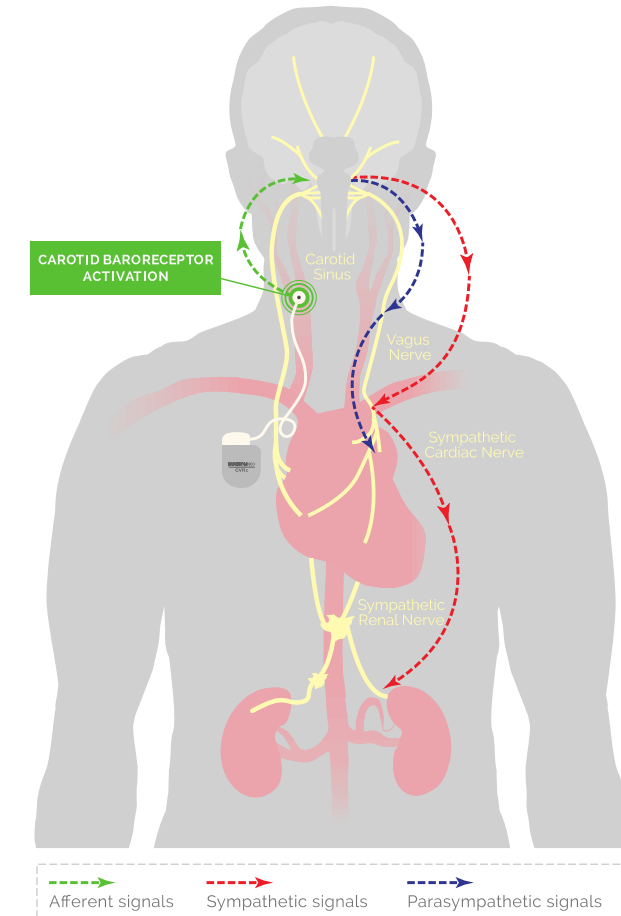
NPP Companies and Technologies

- The NPP represents several stimulation technologies that treat a variety of conditions
- Additional details on each technology are available in the Appendix

Company	Disease State	Technology	HCPSC Coding	Status
LivaNova	Epilepsy and Depression	IPG + Lead	CPT Code 64568 + C1767	N/A
ZOLL Respicardia	Central Sleep Apnea	IPG + Lead	CPT Code 33276 + C1823	TPT Expired 12/31/2022
CVRx	Heart Failure	IPG + Lead	CPT Code 0266T + C1825	TPT Expired 12/31/2023
MicroTransponder	Stroke Recovery	IPG + Lead + External Paired Controller	CPT Code 64568 + C1827	TPT Expires 12/31/2025
SetPoint Medical	Rheumatoid Arthritis	IPG + External Charger	CPT Code 0908T	FDA Approval expected in Q3, 2025

Technology Overview – Carotid Artery Stimulation

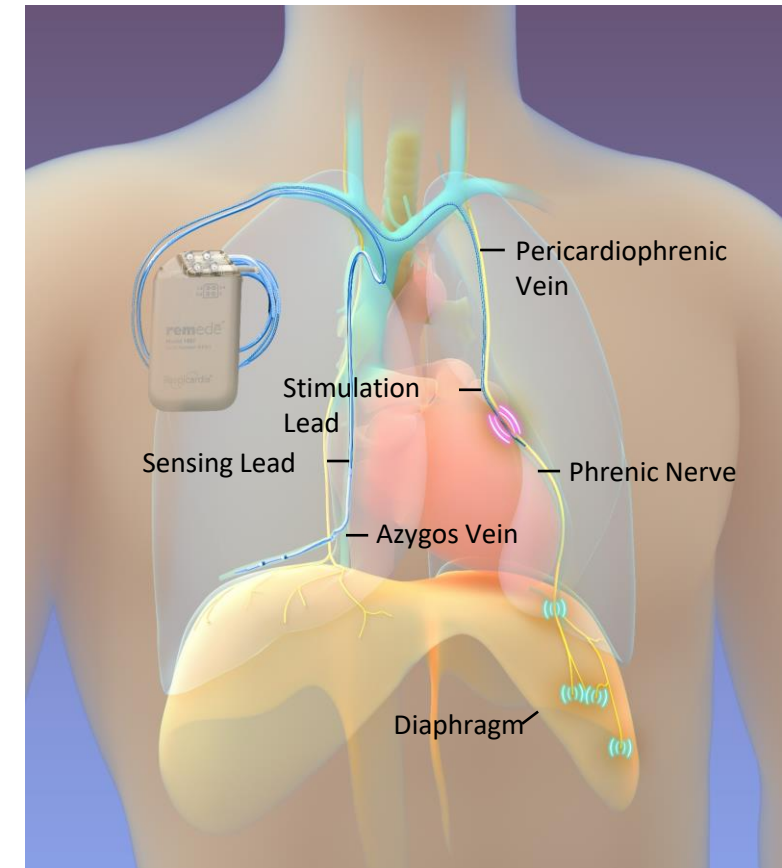
Carotid Artery Stimulation (CVRx)	
Disease State	Heart Failure
Technology	• IPG • Stimulation lead
Coding	• 0266T-0273T • C1825
FDA	• PMA Approval on August 16, 2019 • Breakthrough Designation
CMS	• NTAP effective October 1, 2020 • TPT application effective January 1, 2021



Technology Overview – Phrenic Nerve Stimulation

Phrenic Nerve Stimulation (ZOLL Respicaardia)

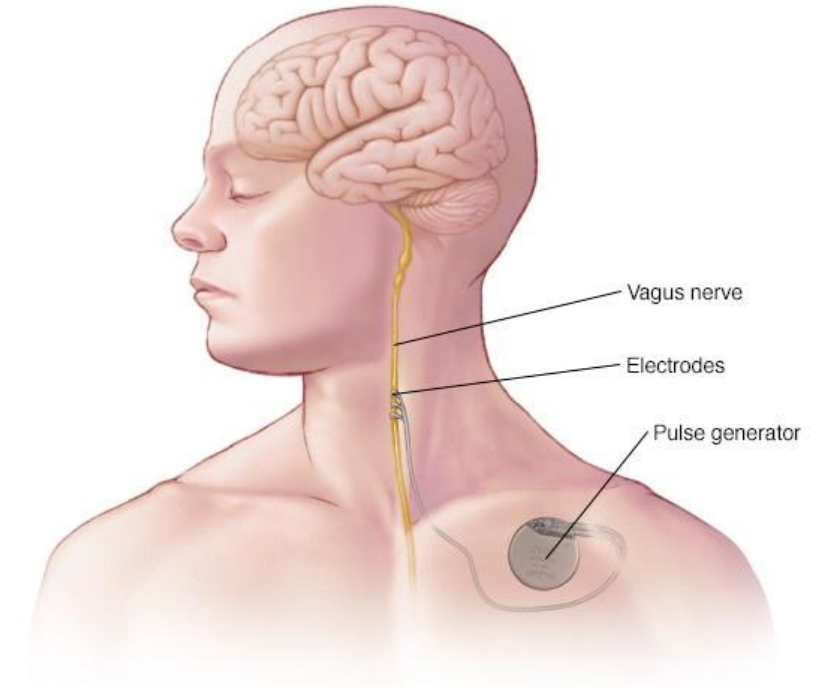
Disease State	Moderate to severe central sleep apnea
Technology	• IPG • Stimulation lead • Sensing lead (if required)
Coding	• 33276-33288 • C1823
FDA	PMA Approval on October 6, 2017
CMS	• NTAP effective October 1, 2018 • TPT effective January 1, 2019



Technology Overview – Vagus Nerve Stimulation

Vagus Nerve Stimulation (LivaNova)

Disease State	• Intractable epilepsy • Treatment resistant depression (TRD)
Technology	• IPG • Stimulation lead
Coding	• 64568 • C1767, C1778
FDA	• PMA Approval on July 16, 1997 (epilepsy) • PMA Approval on July 15, 2005 (depression) • FDA Breakthrough Designation for Heart Failure
CMS	NCD 160.18 covers VNS for epilepsy; CED for treatment resistant depression

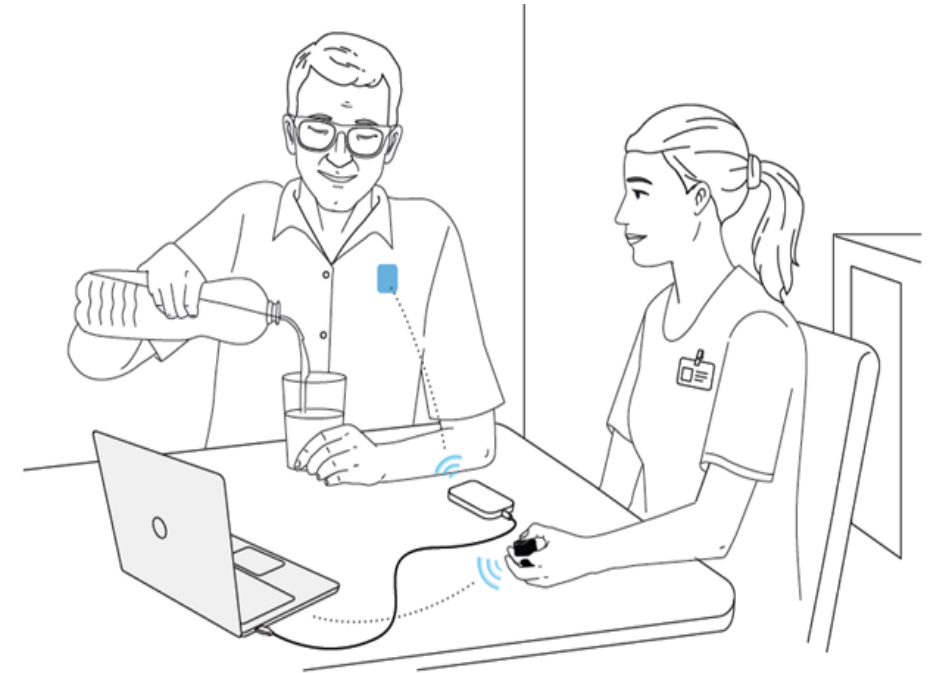


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Technology Overview – Paired Vagus Nerve Stimulation

Paired Vagus Nerve Stimulation (MicroTransponder, Inc.)

Disease State	Chronic upper limb deficit due to stroke
Technology	• IPG • Stimulation lead • Paired stimulation Controller
Coding	• 64568 • C1827
FDA	• PMA Approval on Aug 27, 2021 • Breakthrough Device Designation
CMS	• NTAP effective October 1, 2022 • TPT application effective January 1, 2023



The Vivistim® Paired VNS™ System is intended to be used to stimulate the vagus nerve during rehabilitation therapy in order to reduce upper extremity motor deficits and improve motor function in chronic ischemic stroke patients with moderate to severe arm impairment.

Technology Overview – Vagus Nerve Stimulation for RA

Vagus Nerve Stimulation for Rheumatoid Arthritis (SetPoint Medical)

Disease State	Rheumatoid Arthritis
Technology	• IPG • External Charger
Coding	• 0908T-0912T
FDA	• PMA Approval Expected in Q3, 2025 • Breakthrough Designation
CMS	TBD

