CY 2021 OPPS Device Offset Calculation for CPT 0424T

Advisory Panel on Hospital Outpatient Payment

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Respicardia®

Presentation Summary

- **Presenters:** Collin Anderson, Vice President of Market Access, Respicardia, Inc.
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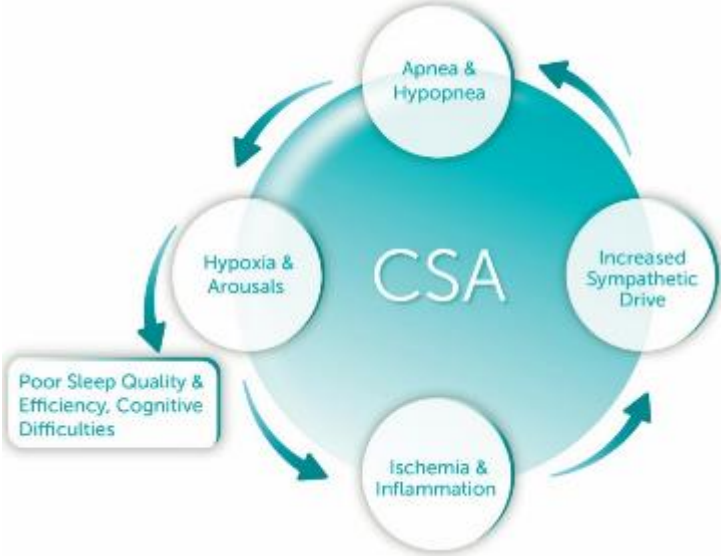
- **CPT/HCPCS Involved:** 0424T
- **APC Involved:** 5465 Neuromodulation and Related Procedures

- **Description of the issue:**
  - CMS has calculated the CY 2021 device related portion (DRP) for CPT 0424T at 99.99% - this compares to the CY 2020 DRP for CPT 0424T of 75.87%.
  - A DRP of 99.99% would indicate that there were no non-device costs for this procedure
- **Clinical description of the service under discussion (with comparison to other services within the APC):**
  - Transvenous phrenic nerve stimulation is comprised of an implantable neurostimulator and two leads to treat moderate to severe central sleep apnea.
  - It is currently described by CPT code 0424T, Insertion or replacement of neurostimulator system for treatment of central sleep apnea; complete system (transvenous placement of right or left stimulation lead, sensing lead, implantable pulse generator) and C1823, Generator, neurostimulator (implantable), nonrechargeable, with transvenous sensing and stimulation leads
- **Recommendations and rationale for change:**
  - The rationale for this change is that a DRP of 99.99% for any procedure is non-sensical since the non-device costs would be ~$0
  - We have been unable to recalculate the DRP of 99.99%
    - Using CMS' methodology for the geometric means for the total cost and device costs for CPT 0424T excluding the costs of C1823, the calculated DRP was 37.8%
    - Including the costs of C1823 results in a revised DRP for CPT 0424T of 75.0%. However, this would require that the costs of C1823 be included in the APC rate setting for CY 2021.
  - We recommend that CMS recalculate the DRP for CPT 0424T and provide the detailed calculations to ensure it was calculated appropriately
- **Potential consequences of not making the change:**
  - The potential consequences of not making this change is that any claim that utilizes the device related portion of CPT 0424T will be in error, as a DRP of 99.99% indicates that there is ~$0 of non-device costs associated with performing the procedure

Central Sleep Apnea (CSA) is a night-time breathing disorder characterized by a disruption in the neural drive to breathe

CSA is due to a loss of neural drive to breathe during sleep[1]



CSA patients undergo hundreds of repeated cycles of oxygen desaturation, arousals and surges in sympathetic drive each night

Nighttime sleep disruptions significantly diminish quality of life[2,3,4,5]

- Severe fatigue
- Excessive daytime sleepiness
- Cognitive impairment
- Depression
- Memory deficits

Untreated CSA significantly increases health risks for these patients

- Significantly higher rates of heart failure and atrial fibrillation[1,6]
- **2x** more likely to have a Heart Failure (HF)-related readmission within 6 months[7]
- **2x** the mortality rate in HF patients[8]

Untreated CSA causes life altering levels of fatigue as well as increased health risks for heart failure and atrial fibrillation

1. Bekfani and Abraham, Europace 2016; 18:1123-24
2. Dempsey JA. Exp Physiol 2005; 90: 13–24,
3. Javaheri S., Dempsey J.A. Compr Physiol. 2013; 3:141–163
4. Brenner, S., et al. Trends Cardiovasc. Med. 2008; 18, 240–247.
5. Flemons WW, Tsai W. J Allergy Clin Immunol 1997; 99:S750-S756
6. Tung et al. J Am Heart Assoc. 2017; e004500. DOI: 10.1161/JAHA.116.004500.Khayat et al. J Card Fail 2012; 18:534-540.
7. Khayat et al. J Card Fail 201218:534-540
8. Khayat et al. Eur Heart J 2015; 23:1463-1469.

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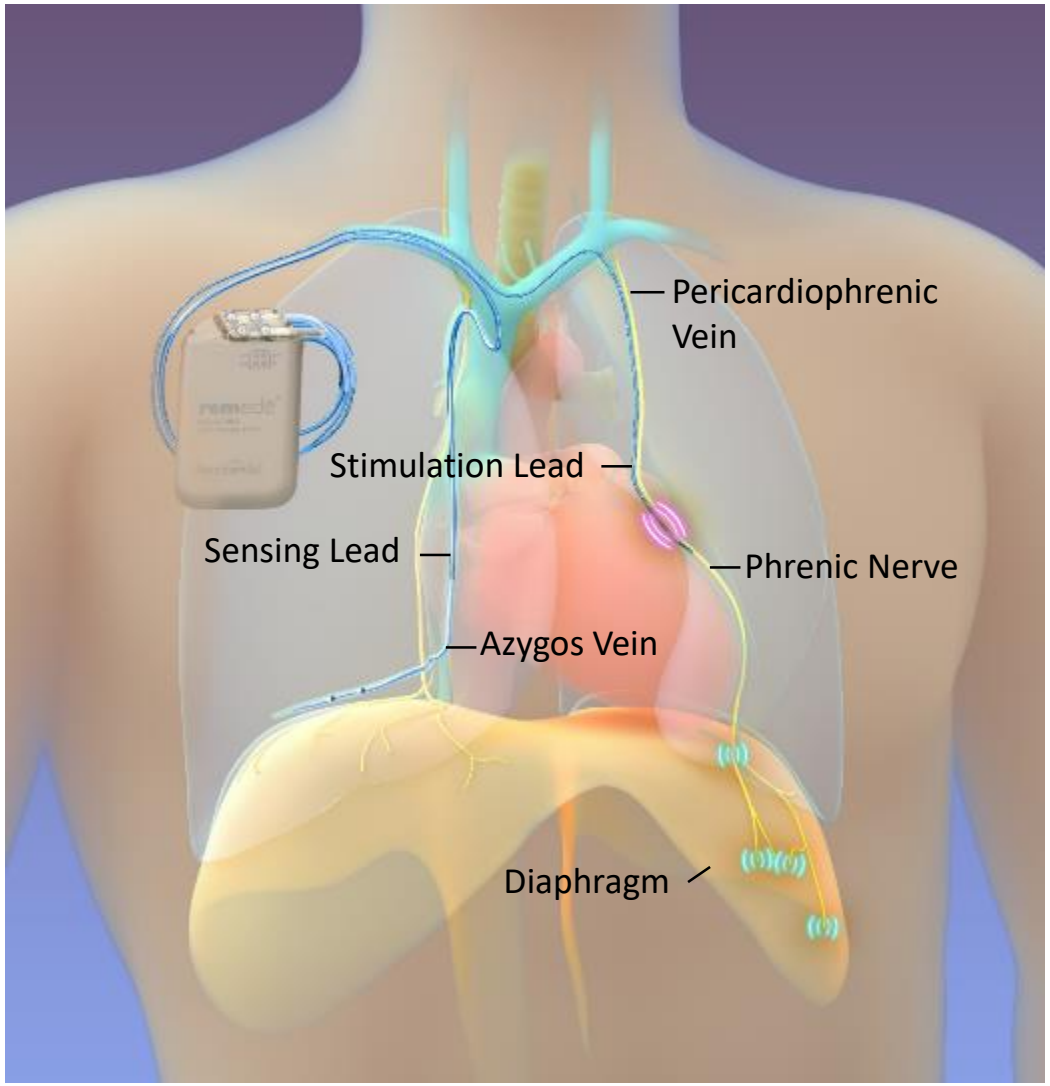
Transvenous phrenic nerve stimulation with the remedē System



- **Fully implantable system** with an indication to treat moderate to severe central sleep apnea in adults; received U.S. FDA PMA approval October 2017
- **Stabilizes breathing** by activating the diaphragm to generate negative pressure in the chest (similar to natural breathing)
- **Turns on automatically at night,** ensuring nightly compliance and adherence over time
- Implanted by cardiac electrophysiologists (EPs)
  - **Pulse generator** implanted below clavicle
  - **Stimulation lead** placed either in left pericardiophrenic or right brachiocephalic vein
  - **Sensing lead** placed in the Azygos vein, helps optimize therapy

1. FDA-Approved Summary of Safety and Effectiveness Data (SSED) for the remedē® System and The remedē System Implant and Clinician Use Manual (P160039) Oct. 6, 2017.

The Proposed Device Related Portion for CPT 0424T in CY 2021 Intimates that there are ~$0 of Non-Device Costs for this Procedure

- CPT code 0424T was effective January 1, 2016 to describe the implantation of a transvenous phrenic nerve stimulation system to treat central sleep apnea
- Since 2018, CMS has calculated a device related portion for CPT code 0424T. The DRP has been consistent until CY 2021:

CPT / APC	Description	CY 2018 Final	CY 2019 Final	CY 2020 Final	CY 2021 Proposed
0424T	Insj/rplc nstim apnea compl	77.20%	74.47%	75.87%	99.99%
63685	Insrt/redo spine n generator	82.77%	82.90%	82.61%	82.45%
64568	Inc for vagus n elect impl	87.12%	85.73%	86.29%	86.13%
5464	Level 4 Neurostimulator and Related Procedures APC	83.71%	83.66%	83.30%	Not Available

Device Offset Calculations for 0424T

CY 2020 Device Offset Calculations Compared to OPPS Addendum P

HCPCS	Description	OPPS ADDENDUM P			CALCULATED DEVICE OFFSET				
		SI	APC	Device Offset Percentage	Geometric Mean Cost for HCPCS 0424T (A)	Geo mean cost of ALL singles without device lines packaged (B)	Device cost (A-B)	Calculated device proportion (A-B)/B	Difference of Addendum P and calculated offset
0424T	**Insj/rplc nstim apnea compl**	**J1**	**5464**	**75.9%**	**$25,737.70**	**$6,211.62**	**$19,526.08**	**75.87%**	**-0.01%**
64568	Inc for vagus n elect impl	J1	5464	86.3%	$37,641.68	$5,162.52	$32,485.74	86.29%	0.00%
C9600	Perc drug-el cor stent sing	J1	5193	39.8%	$9,527.93	$5,742.13	$3,796.66	39.80%	0.06%
33208	Insrt heart pm atrial & vent	J1	5223	64.0%	$10,929.09	$3,940.60	$6,991.40	63.95%	-0.03%
33249	Insj/rplcmt defib w/lead(s)	J1	5232	75.3%	$32,902.35	$8,135.16	$24,768.60	75.28%	-0.01%

Using CMS' payment methodology, the calculated DRP for 0424T and other procedures matches Addendum P

CY 2021 Device Offset Calculations Compared to OPPS Addendum P

HCPCS	Description	OPPS ADDENDUM P			CALCULATED DEVICE OFFSET				
		SI	APC	Device Offset Percentage	Geometric Mean Cost for HCPCS 0424T (A)	Geo mean cost of ALL singles without device lines packaged (B)	Device cost (A-B)	Calculated device proportion (A-B)/B	Difference of Addendum P and calculated offset
0424T	**Insj/rplc nstim apnea compl**	**J1**	**5465**	**100.0%**	**$16,862.96**	**$10,496.04**	**$6,366.92**	**37.76%**	**-62.24%**
64568	Inc for vagus n elect impl	J1	5465	86.1%	$37,961.95	$5,297.18	$32,682.68	86.05%	-0.1%
C9600	Perc drug-el cor stent sing	J1	5193	39.1%	$9,619.25	$5,856.35	$3,769.86	39.16%	0.06%
33208	Insrt heart pm atrial & vent	J1	5223	62.9%	$11,047.40	$4,098.21	$6,956.27	62.93%	0.01%
33249	Insj/rplcmt defib w/lead(s)	J1	5232	74.6%	$33,680.10	$8,563.39	$25,123.42	74.58%	-0.01%

Repeating this methodology for CY 2021, the calculated DRP does not match what is listed in Addendum P for CPT 0424T despite other DRPs matching CMS' calculations

Calculating Device Offset for 0424T with C1823 Included as Packaged

HCPCS	Description	OPPS ADDENDUM P			CALCULATED DEVICE OFFSET (OPTION 2)			
		SI	APC	Device Offset Percentage	Geometric Mean Cost for HCPCS 0424T (A)	Geo mean cost of ALL singles without device lines packaged (B)	Device cost (A-B)	Calculated device proportion (A-B)/B
0424T	**Insj/rplc nstim apnea compl**	**J1**	**5465**	**99.99%**	**$41,912.77**	**$10,496.04**	**$31,416.73**	**74.96%**

Using an alternative methodology by packaging costs of C1823 with 0424T results in a DRP that is similar to CY 2020, but still varies significantly from Addendum P

Request Summary

- The proposed CY 2021 DRP of 99.99% for CPT 0424T does not recognize any non-device costs associated with the procedure and is significantly different from the DRP of the procedure over the previous three years (74-77% for CY 2018 - CY 2020)
- It has not been possible to recalculate how CMS calculated the DRP of 99.99% for CPT 0424T despite the DRP of other device intensive procedures appear appropriate
- To correctly calculate the CY 2021 device related portion for CPT 0424T, we recommend CMS re-calculate the DRP for this procedure and provide the detailed calculations to ensure it was calculated appropriately