

CY 2023 APC Request for CPT 0424T

Advisory Panel on Hospital Outpatient Payment
August 22-23, 2022

ZOLL[®]
an Asahi Kasei company

Presentation Summary

- **Presenter:** Collin Anderson, President, ZOLL Respicardia
- **CPT/HCPCS Involved:** 0424T, C1823
- **APC Involved:** 5465 Neuromodulation and Related Procedures

Description of the issue:

- Phrenic nerve stimulation for treating central sleep apnea (CSA, described by CPT 0424T) fills an unmet clinical need for Medicare beneficiaries
- CPT 0424T has a reported \$52,471 cost as represented in the geometric mean cost (GMC) and proposed APC 5465 payment of \$29,932 for CY23
- This creates a (\$22,539) disparity between the procedure costs and Medicare payment, which will significantly limit Medicare beneficiary access to this therapy

Clinical description of the service under discussion:

- Phrenic nerve stimulation for CSA (The remedē System) is comprised of an implantable neurostimulator and lead(s) to treat a small patient population with moderate to severe central sleep apnea
- CPT code 0424T describes the insertion of the complete system (transvenous placement of stimulation lead, sensing lead, implantable pulse generator)

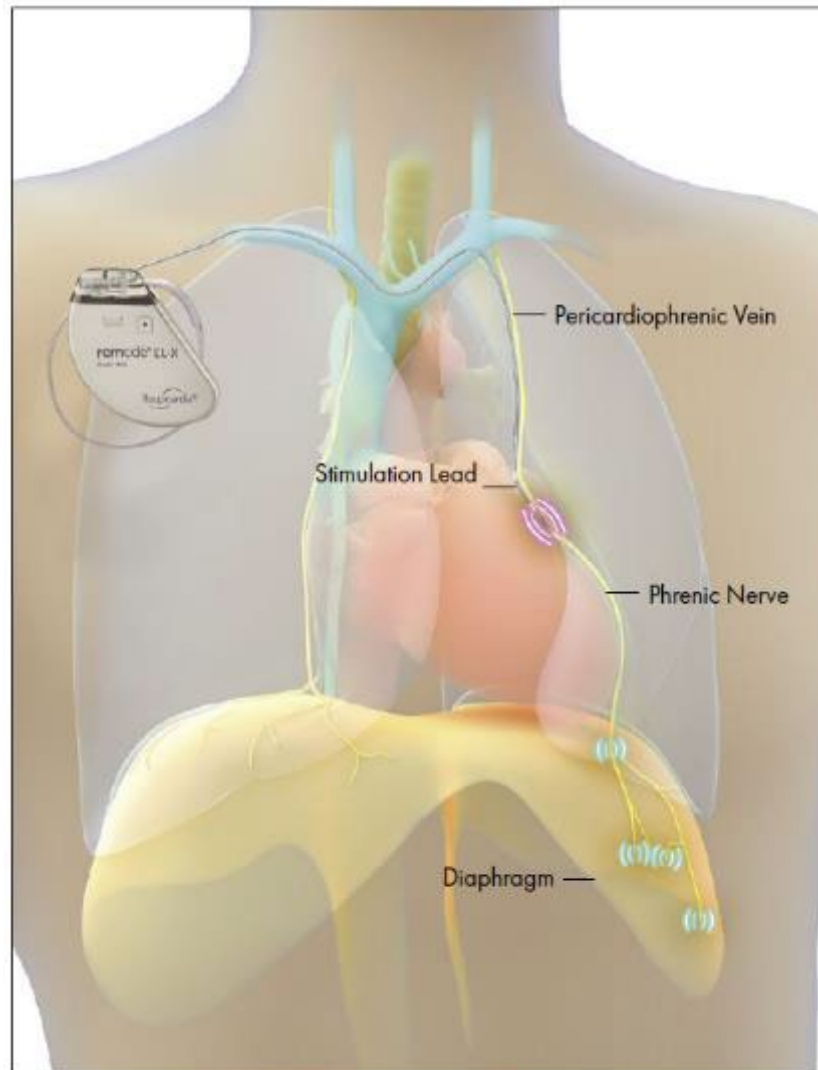
Recommendations and rationale for change:

- We support the creation of a Level 6 Neurostimulator and Related Services APC to more appropriately reflect the hospital resources required for these neurostimulation therapies
- However, we request the Panel recommend CMS temporarily assign CPT code 0424T to New Technology APC 1581 or 1595. Either APC more appropriately sets payment consistent with the hospital reported cost of this procedure.

Potential consequences of not making the change:

- Not providing adequate payment to hospitals for this procedure will create a strong disincentive and discourage Medicare beneficiary access to care.

Transvenous phrenic nerve stimulation with the remedē System



- Untreated CSA causes **life altering levels of fatigue** as well as increased health risks for patients with heart failure and atrial fibrillation
- CSA is a **relatively rare disease** found in only 1.3% of sleep apnea diagnoses with only a subset indicated for phrenic nerve stimulation
- remedē is a **fully implantable system** with an indication to treat moderate to severe central sleep apnea in adults; received U.S. FDA PMA approval October 2017
- 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 (as needed)

The procedure cost of over \$52k is significantly higher than the cost of any other procedure within the Level 5 Neurostimulator APC

- The CY 2021 claims data shows a procedure geometric mean cost (GMC) of \$52,471, which is significantly higher than the GMC of any other procedure within the Level 5 Neurostimulator APC
- We understand the APC system is meant to average out procedures. However, the remedē System is unique in that it is, and will continue to be, a low volume procedure which is adversely impacted by this methodology and inhibits consideration under the “2 times rule.”
 - The **lowest procedure cost in the APC 5465 is \$28,126** (CPT code 61886) with over 3,000 claims
 - The **procedure cost for CPT 0424T is \$52,471 and will never exceed 1,000 claims** given the small prevalence of CSA
 - CSA is found in only 1.3% of sleep apnea diagnoses; of these diagnosed patients, an estimated 400-600 will be indicated for phrenic nerve stimulation each year
- This significant disparity may also trigger frequent outlier payments given the geometric mean cost (GMC) of the procedure (\$52,471) exceeds the CY 2023 proposed outlier threshold.
 - GMC of \$52,471 > \$52,381 (1.75x the APC 5465 payment of \$29,932), and
 - GMC of \$52,471 > \$38,282 (APC 5465 payment of \$29,932 + \$8,350)

Keeping CPT 0424T in APC 5465 creates a significant disparity between the cost of the implant procedure and Medicare payment, which will limit therapy access

- While we support the creation of a level 6 Neurostimulator and Related Services APC, there is still a significant disparity between the \$52,471 geometric mean cost (GMC) of the implant procedure (CPT code 0424T) and the GMC of the proposed Level 6
- If CPT code 0424T were included in a newly created Level 6 APC, or remains in the existing Level 5 APC, Medicare beneficiary access will be significantly limited due to significant underpayment
- We request CMS temporarily assign CPT code 0424T to New Technology APC 1581 or 1595 to provide appropriate and consistent payment for this new procedure until sufficient claims data is gathered to assign it to a more appropriate APC

Geometric Mean Cost For CPT 0424T	APC	CY 2023 Potential Payment	Difference
\$52,471	5465 Currently Proposed	\$29,932	(\$22,539)
\$52,471	5466 as Published by CMS	\$33,947 <i>APC GMC</i>	(\$18,524)
\$52,471	New Technology – Level 44 APC 1581 or 1595	\$55,000	\$2,529

Request Summary

We request the Panel recommend CMS temporarily assign CPT code 0424T to New Technology APC 1581 or 1595 for CY 2023, given the disparity between the \$52,471 procedure cost and the proposed APC 5465 payment of \$29,932.

- The New Technology APC 1581 or 1595 pay bands more appropriately provide payment to hospitals consistent with the claims for CPT 0424T to ensure continued Medicare beneficiary access.
- This request is for a temporary assignment while additional claims data is analyzed for the new therapies in the neurostimulator APC group.
- Not providing adequate payment to hospitals for this procedure will create a strong disincentive and discourage the very access to care for Medicare beneficiaries that CMS aims to facilitate.