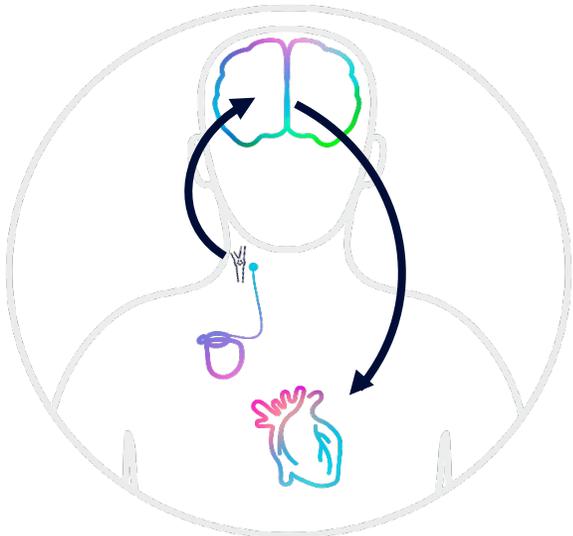
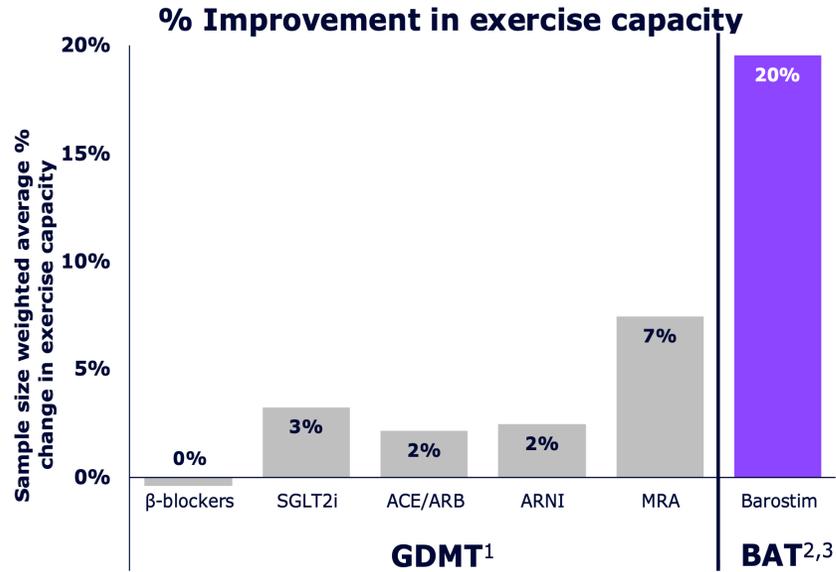


CY 2025 APC Reclassification Request for CPT Code 0266T

August 26/27, 2024



Baroreflex activation with the Barostim System in Patients Suffering from Heart Failure



- Most patients with heart failure, even after receiving optimal guideline directed medical therapy, continue to suffer from poor quality of life and substantial limitation in functional capacity
- A very **small subset of heart failure patients (4.2%) meet the Barostim eligibility criteria** as approved by FDA
 - Furthermore, only a **small fraction of Heart Failure patients receives device therapies**, reducing the target market potential of Barostim to a very small group of patients
- Barostim System is fully implantable, comprised of an implantable pulse generator and lead placed on the carotid sinus
 - Indicated to treat heart failure symptoms in patients with low ejection fraction of 35% or less, an NT-proBNP less than 1600 pg/ml, and who are not candidates to receive a cardiac resynchronization therapy (CRT)
- Barostim System is prescribed by a heart failure cardiologist, and implanted by a vascular surgeon, under full anesthesia:
 - Pulse generator implanted below clavicle
 - Carotid sinus lead implanted on top of carotid bifurcation

Barostim received Breakthrough Device Designation from the FDA, and NTAP and TPT from CMS

- **FDA**

- Received breakthrough designation in June 2015
- Received Premarket Approval (P180050) in August 2019

- **CMS**

- NTAP effective October 1, 2020 – September 30, 2022
- TPT effective January 1, 2021, expired Dec 2023
- 2024 - CPT code 0266T for the implant procedure is assigned to New Tech APC 1580
 - HOP Panel in August 2023 recommended to CMS that 0266T be reclassified to APC 1580
- 2025 – CMS proposes to reclassify 0266T to APC 5465 (Level 5 Neurostimulator)
 - CMS requested comments regarding a Level 6 Neurostimulator APC

The GMC of the implant procedure (0266T) is significantly higher than the proposed CY 2025 payment for APC 5465, Level 5 Neurostimulator & Related Services

- The proposed CY 2025 APC assignment for the implant procedure creates significant financial disincentive for hospitals to offer the Barostim System to Medicare patients:
 - This represents a >31% **decrease** in payment from 2024

CMS-1786-P	Single Claims	Payment
Proposed APC 5465 Payment for CY 2024	n=18,501 (100%)	\$30,197
Geometric Mean Cost of CPT Code 0266T	n=256 (1.4%)	<u>\$41,069</u>
Difference – Financial Loss to the Hospital per Procedure		(\$10,872)

- We understand the OPSS is not meant to be a fee schedule and payment is meant to “average out” across all the procedures in the APC
- However, given the very low volume of this procedure, the Barostim System will continue to be grossly under-paid relative to the cost of the procedure
 - There is also the issue of significant variability in reporting low volume new technology
- We are concerned that this level of financial loss will restrict access of the technology to Medicare beneficiaries
- In August of 2023, when this procedure was in same position the HOP Panel unanimously recommended that CMS place 0266T in New Technology APC 1580 to ensure continued beneficiary access

We request that the HOP Panel Recommend CPT Code 0266T remain in APC 1580 based on the GMC of the Procedure

- We believe the most appropriate APC assignment is the New Technology APC 1580
- This APC more appropriately reimburses for the implant procedure based on hospital reported costs
- CMS has reassigned technologies to New Technology APCs when there is not a logical clinical APC assignment (e.g., 0100T, 0424T/33276) based on cost
 - Given the low volume of claims for this procedure, it is impossible to impact APC 5465 and would be inappropriate to place in that APC
 - We believe that ultimately CMS should create a Level 6 Neurostimulator APC – as they have done with other even lower volume APCs with lower cost disparities.
- We contend that Barostim System is in a similar situation given the absolute difference in the total cost of the procedure compared to the APC payment rate

Request Summary

- **We request that HOP Panel vote to recommend CMS leave CPT code 0266T in New Technology APC 1580 for CY 2025 given the disparity between the \$41,069 approximate procedure cost and the current APC 5465 payment of \$30,197**
- The New Technology APC 1580 provides more appropriate payment to hospitals consistent with the reported cost of CPT 0266T to ensure continued Medicare beneficiary access
- 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
- Barostim has shown significant quality of life benefit as well as a 74% reduction in the rate of advance HF interventions (Heart Transplants, LVAD, CCM, CRT, PAP Monitoring) for those patients receiving Barostim as compared to control.