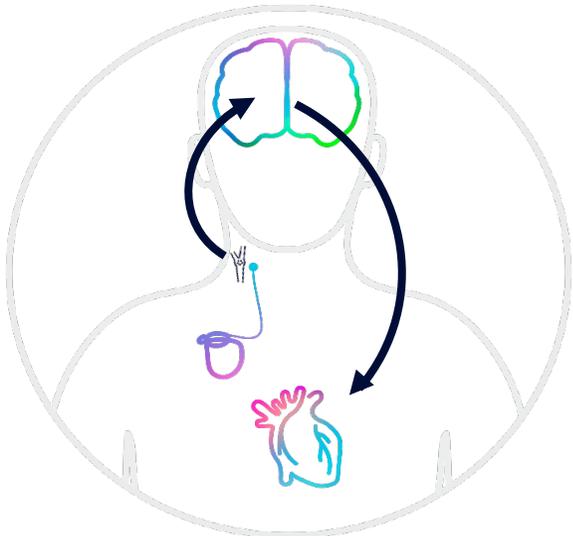
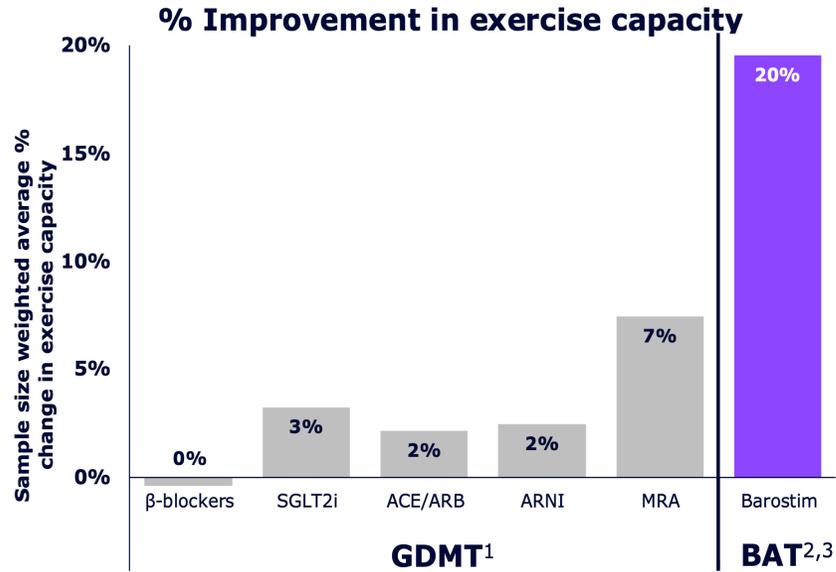


CY 2024 APC Reclassification Request for CPT Code 0266T

August 21, 2023



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 -- *currently expired*
- TPT effective January 1, 2021
 - Device category C1825 for de novo system implants
 - Scheduled to expire December 31, 2023
- CPT code 0266T for the implant procedure is assigned to APC 5465, Level 5 Neurostimulator and Related Procedures

The GMC of the implant procedure is significantly higher than the proposed CY 2024 payment for APC 5465, Level 5 Neurostimulator & Related Services

- The Barostim System received Transitional Pass-Through effective January 1, 2021, which will expire December 31, 2023
 - Given TPT is expiring, the hospital claims in the CY 2024 proposed rule represent the total cost of the procedure
- The proposed CY 2024 APC assignment for the implant procedure creates significant financial disincentive for hospitals to offer the Barostim System to Medicare patients:

CMS-1786-P	Single Claims	Payment
Proposed APC 5465 Payment for CY 2024	n=17,121 (100%)	\$30,355
Geometric Mean Cost of CPT Code 0266T	n=96 (0.6%)	<u>\$45,996</u>
Difference – Financial Loss to the Hospital per Procedure		(\$15,641)

- 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
- We are concerned that this level of financial loss will restrict access of the technology to Medicare beneficiaries

Request that the HOP Panel Recommend CMS Reclassify CPT Code 0266T to APC 1580 based on the GMC of the Procedure

- We believe that a more appropriate APC assignment is the New Technology APC 1580
- This APC more appropriately reimburses for the implant procedure based on hospital reported costs:

APC Assignment		CY 2024 Proposed Payment	Geometric mean cost for CPT 0266T	CY 2024 Proposed Payment	Absolute Difference	Percent Difference of GMC Compared to Payment
Current	APC 5465	\$30,335	\$45,996	\$30,335	(\$15,641)	(51.6%)
Proposed	APC 1580	45,001	\$45,996	\$45,000	(\$955)	(2.1%)

- When appropriate, CMS has reassigned technologies to New Technology APCs when TPT has expired and there is not a logical clinical APC assignment (e.g., 0100T, 0424T) based on cost
- We contend that the 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 reassign CPT code 0266T to New Technology APC 1580 for CY 2024 given the disparity between the \$45,996 procedure cost and the current APC 5465 of \$30,3545**
- 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