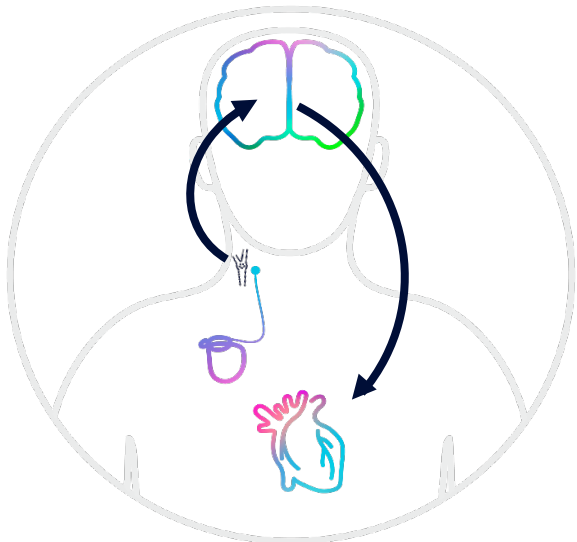
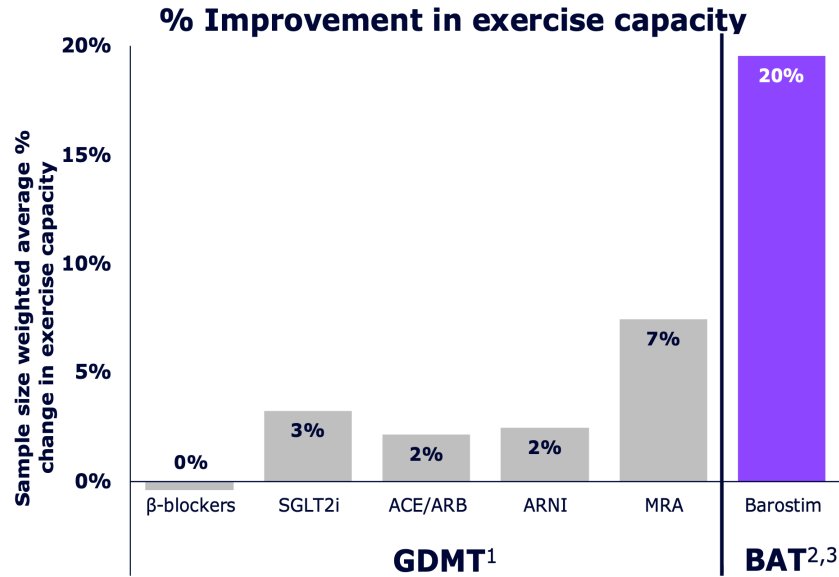


# CY 2024 APC Reclassification Request for CPT Code 0266T

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		<b>(\$15,641)</b>

- We understand the OPPS 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