Office of Medicaid
BOARD OF HEARINGS

Appellant Name and Address:

[redacted]

Appeal Decision:	Denied	**Appeal Number:**	2402115
Decision Date:	3/20/2024	**Hearing Date:**	03/14/2024
Hearing Officer:	Thomas J. Goode		

Appearance for Appellant:
Pro se

Appearance for Cambridge Health Alliance:
Kathryn Tylander, Manager of Quality and Compliance
Susan Donnelly, Director of Operations
Jonathan Burns, Medical Director

The Commonwealth of Massachusetts
Executive Office of Health and Human Services
Office of Medicaid
Board of Hearings
100 Hancock Street, Quincy, Massachusetts 02171

APPEAL DECISION

Appeal Decision:	Denied	**Issue:**	Prior Authorization
Decision Date:	3/20/2024	**Hearing Date:**	03/14/2024
CHA PACE Reps.:	Kathryn Tylander, et al.	**Appellant Rep.:**	Pro se
Hearing Location:	Remote	**Aid Pending:**	No

Authority

This hearing was conducted pursuant to Massachusetts General Laws Chapter 118E, Chapter 30A, and the rules and regulations promulgated thereunder.

Jurisdiction

Through a notice dated January 10, 2024, and following a standard internal appeal, Cambridge Health Alliance (CHA) PACE (Program of All-Inclusive Care for the Elderly) denied Appellant's request for a Barostim Baroreflex Activation Therapy (BAT) procedure (130 CMR 450.204, 519.007(C), and Exhibit 1). Appellant filed this appeal in a timely manner on February 12, 2024 (130 CMR 610.015(B) and Exhibit 2). Denial of assistance by a PACE program is valid grounds for appeal (130 CMR 610.032, 42 CFR 460.124(b)).

Action Taken by CHA PACE

CHA PACE denied Appellant's request for a Barostim Baroreflex Activation Therapy (BAT) procedure because it determined that the Barostim device requested is experimental and therefore does not meet medical necessity criteria. CHA PACE also determined that Appellant does not meet clinical specifications for the Barostim device requested. CHA PACE also denied the procedure because the provider and facility is outside the CHA PACE service area.

Issue

The appeal issue is whether CHA PACE correctly denied Appellant's request for a Barostim Baroreflex Activation Therapy (BAT) procedure because it determined that the Barostim device requested is experimental and therefore does not meet medical necessity criteria. A second issue is whether Appellant meets clinical specifications for the Barostim device. A third issue is whether CHA PACE correctly denied the procedure because the provider and facility is outside the CHA PACE service area.

Summary of Evidence

The Cambridge Health Alliance Program of All-Inclusive Care for the Elderly (hereinafter CHA PACE) representatives testified that CHA PACE is a managed Medicare & Medicaid replacement program. The CHA Interdisciplinary Team (IT) must review and authorize all care and services, uses clinical judgment on a case-by-case basis, and Medicare & Medicaid guidance to make medical necessity determinations. Services that are not covered by CHA PACE include any service not authorized by the IT, even if it is a covered benefit, unless the service is for emergency care (Exhibit 4, p. 9). By notice dated January 10, 2024, and following a denial of an internal appeal decision issued on December 12, 2023, CHA PACE informed Appellant that his request for coverage of a Barostim implantation procedure at Portsmouth Regional Hospital was denied because the IT determined, in conjunction with an independent third-party reviewer, that the Barostim device requested is still experimental and undergoing longer term trials (Exhibit 4, p. 8). Additionally, the IT determined that Appellant may not meet clinical criteria based on guidelines from the device manufacturer (Exhibit 1, p. 14). A third-party appeal review dated January 3, 2024 was completed by Richard Kalish, MD, MPH, MS, Medical Director, Elder Service Plan of Harbor Health. The third-party review describes Appellant as a [redacted]-year-old male, with diagnoses including calcification of aorta, coronary artery disease (CAD) with history of myocardial infarct, history of coronary artery bypass grafting (CABG) mild ascending aorta dilation, history of Non-ST-Elevation Myocardial Infarction (NSTEMI), congestive heart failure (CHF) with cardiomyopathy, history of pulmonary embolism (PE), vitamin D deficiency, secondary hyperaldosteronism, secondary hyperparathyroidism, GERD, drug induced constipation, CKD stage 4, chronic pain syndrome, restless leg syndrome, paraparesis, neuromyopathy, obstructive sleep apnea (OSA), iron deficiency, and septic shock. The decision to deny the requested service was based on a determination that the Barostim procedure is still experimental and undergoing longer term trials. Secondarily, the reviewer determined that Appellant does not qualify for the procedure from a clinical standpoint since his NT-proBNP[1] has been greater than 1600 pg/ml 8 out of 10 times in 2023, including a value of 3109 pg/ml on 10/5/2023. Barostim specifies that the value should be

[1] See https://medlineplus.gov/lab-tests/natriuretic-peptide-tests-bnp-nt-probnp/: Natriuretic Peptide Tests (BNP, NT-proBNP) Natriuretic peptides are proteins that your heart and blood vessels make. Natriuretic peptide tests measure the amount of these proteins in a sample of your blood. They are mainly used to help confirm or rule out heart failure in people who have symptoms.

less than 1600 pg/ml. The reviewer also cited substantial risks associated with the procedure. (Exhibit 1, p. 13)

The CHA PACE representatives testified that Appellant has been enrolled in CHA PACE since January 1, 2020. The CHA PACE enrollment agreement specifies that experimental medical surgical or other health treatments are not covered by CHA PACE and are precluded by Medicare and MassHealth regulations (Exhibit 4, p. 15). The Barostim Neo System is an experimental treatment that is currently in clinical trials. The CHA PACE representatives pointed to manufacturer's company website which states "CAUTION: Investigational device. Limited by Federal Law (or United States) law to investigational use" (Exhibit 4, p. 46). The manufacturer of the device states "[t]he BAROSTIM NEO System is indicated for the improvement of symptoms of heart failure—quality of life, six-minute hall walk and functional status—for patients who remain symptomatic despite treatment with guideline-directed medical therapy, are NYHA Class III or Class II (who had a recent history of Class III), have a left ventricular ejection fraction ≤ 35%, a NT-proBNP < 1600 pg/ml" (Id., p. 46).

CHA PACE testified that baroreflex activation therapy (BAT) is a device-based approach that consists of an implanted pulse generator that is implanted in the pectoral region, external programming system, and leads placed adjacent to the carotid sinus to deliver electrical pulses to the carotid baroreceptors. The Barostim Neo System is a specific BAT device that received FDA approval on August 16, 2019 (Id., p. 49). The FDA approval requires Barostim to continue to trial the device for safety and long-term effects. CHA PACE documented current clinical trials in progress and information regarding the trial on clinicaltrials.gov (Id., p. 54). CHA PACE testified to an article published by The American College of Cardiology on December 2, 2022, which states that "given that the currently available evidence is insufficient to derive conclusion regarding reduction in mortality of hospitalization for HF with BAT, the contemporary European and American HF guidelines do not provide specific recommendations regarding the use of BAT in patients with HF" (Id., p. 72). An additional article, "Novel Non-pharmaceutical Advancements in Heart Failure Management: The Emerging Role of Technology" accepted to Current Cardiology Reviews in April of 2021 notes the: "Barostim Neo System is currently approved for use in Europe and recently received pre-market FDA approval in the U.S. A preliminary study has a 59% probability of being cost-effective, but further information is needed" (Id., pp. 75, 79). CHA PACE testified that other insurance companies such as Regency have noted that there is currently not enough evidence to support the use of baroreflex stimulation devices. Regency included in its Medial Policy Manual "[t]here is not enough evidence to determine the overall impact of baroreflex stimulation devices for the treatment of any condition. Therefore, use of baroreflex stimulation is considered investigational for all indications, including but not limited to resistant hypertension and heart failure (Id., pp. 88-89). In addition, Blue Cross Blue Shield of Massachusetts lists baroreflex stimulation devices as investigational; and their policy states "the evidence is insufficient to determine that the technology results in an improvement in the net health outcome" (Id., p. 94).

The CHA PACE representatives also testified that in addition to the experimental status of the Barostim Neo System, Appellant's NT-proBNP measurements have exceeded manufacturer specifications which state that the value should be less than 1600 pg/ml.[2] CHA also testified to the risks associated with the procedure (Id., pp. 4-5). CHA PACE also testified that out of area care is generally only authorized in emergency situations, and only when a participant cannot return to the service area to receive care (Exhibit 4, p. 14). The requested procedure is not available within the CHA PACE network, including its contracted tertiary hospital, Beth Israel Deaconess Medical Center. While the Boston area includes several tertiary hospitals that are not contracted, CHA PACE will often approve procedures within the Boston area hospitals because of their close proximity to CHA PACE. However, CHA PACE does not authorize care at hospitals outside of Boston or the Boston metro area because of the challenges related to coordinating care at such great distances from the PACE service area given the complexity and frailty of CHA PACE participants and the need to coordinate follow-up care.

Appellant testified that in August 2023, the CHA PACE team told him that he was approved for the procedure. Appellant pointed to an evaluation dated September 6, 2023 from Glenn LaMuraglia, MD, which was completed at Mass. General Hospital (MGH), and which Appellant described as an approval for the Barostim implant procedure.[3] Appellant explained that he learned that MGH had stopped doing the procedure because it was not being paid by insurers, and that's when he found Dr. Wilson in Portsmouth, NH who requested the procedure on his behalf. Appellant asserted that the CHA PACE team told him that the procedure was approved for the New Hampshire provider, then Dr. Burns told him the procedure was denied. Appellant stated that the CHA PACE team encouraged him to get tested at MGH for the procedure. Appellant asserted that although MassHealth isn't paying for the procedure, at least 20 other insurers are paying for the procedure (Exhibit 2, p. 14). Appellant stated that elevated NT-proBNP values were taken when he was hospitalized several times, and each time fluid had to be removed. He added that values below 1600 are based on regular blood testing. Appellant testified to a letter from Lana Tsao, MD, a cardiologist at MGH, who advocated for him to have the procedure (Exhibit 2, pp. 6-10). Appellant disagreed with the CHA PACE decision to deny payment for the service because the Barostim device was approved by the FDA in 2019 (Exhibit 2, pp. 20-24 & Exhibit 4, pp. 49-53). Appellant stated that his goal in pursuing the procedure is to exercise more and have a better quality of life. He pointed to a Service Inquiry Processing Form, Section 2, which indicates that the procedure was not recommended and should be changed because the CHA PACE team did approve the procedure for him (Exhibit 1 p. 6). Appellant maintained that he was told by the CHA PACE team that the procedure was approved, but it was delayed because he had bedsores, and then the procedure was unexpectedly denied in January 2024.

Appellant submitted an article: "Baroreflex Activation Therapy in Patients With Heart Failure With Reduced Ejection Fraction (Exhibit 2, pp. 29-41); A Product Brief: "Barostim Neo System

[2] See NT-proBNP test results, Exhibit 4, pp. 105-117, and Id., p. 3.

[3] See Exhibit 5 submitted by Appellant and Exhibit 6 submitted by CHA PACE for a more complete copy of the September 6, 2023 assessment.

(CRVx, Inc.) for Treating Heart Failure" (Id., 42-49); an article "Barostim NEO-Baroreflex Activation Therapy for the Treatment of Systolic Heart Failure (Id., pp. 16-18); and Summary of Safety and Effectiveness DATA (SSED) (Id., p. 19) which Appellant asserts show the Barostim implant procedure is safe and effective. Appellant also included a letter dated December 13, 2023 from William Wilson, MD, the physician who was going to perform the procedure at Portsmouth Regional Hospital (Exhibit 2, pp. 11-15)

Dr. Burns testified that Dr. LaMuraglia is an outside cardiologist not contracted with CHA PACE, who provide a recommendation for the procedure, but authorization would have to issue through the CHA PACE process undertaken by the IT. The CHA PACE representatives explained that CHA PACE was exploring the possibility of authorizing the procedure for Appellant at MGH, and MGH revealed to CHA PACE that it was no longer getting paid by insurers to perform the procedure. CHA PACE testified that some insurers are partially paying for the procedure and billing patients for the balance. CHA PACE testified that Dr. Tsao is not a CHA PACE affiliated provider. CHA PACE testified that the Service Inquiry Processing Form is an internal form that directs the IT to timely process determination requests. The CHA PACE representatives maintained that there was no previous approval that was revoked. Dr. Burns testified that he did have conversations with Appellant about the procedure, and spoke with Dr. Tsao, learned more about the small number of cases that she had performed, and that she was no longer performing the procedure. Dr. Burns added that he was also advised by the CHA PACE cardiologist that the procedure is not the standard of care and is not part of any of the American College of Cardiology algorithms or professional guidelines. Dr. Burns confirmed that CHA PACE reviewed the materials submitted by Appellant which did not change the CHA PACE determination.

Findings of Fact

Based on a preponderance of the evidence, I find the following:

1. Appellant has been enrolled in CHA PACE since January 1, 2020.

2. The CHA PACE Program is a comprehensive health program that is designed to keep frail, older individuals who are certified eligible for nursing-facility services living in the community. A complete range of health-care services is provided by one designated community-based program with all medical and social services coordinated by a team of health professionals.

3. The CHA Interdisciplinary Team must review and authorize all care and services and uses clinical judgment on a case-by-case basis and Medicare & Medicaid guidance to make medical necessity determinations.

4. Services that are not covered by CHA PACE include any service not authorized by the Interdisciplinary Team, even if it is a covered benefit, unless the service is for emergency

care.

5. Baroreflex activation therapy (BAT) is a device-based approach that consists of an implanted pulse generator that is implanted in the pectoral region, external programming system, and leads placed adjacent to the carotid sinus to deliver electrical pulses to the carotid baroreceptors.

6. By notice dated January 10, 2024, and following a denial of an internal appeal issued on December 12, 2023, CHA PACE informed Appellant that his request for coverage for a non-emergent Barostim implantation procedure at Portsmouth Regional Hospital was denied because the Interdisciplinary Team determined, in conjunction with an independent third-party reviewer, that the Barostim device requested is still experimental and undergoing longer term trials.

7. Appellant is a [redacted]-year-old male with diagnoses including calcification of aorta, coronary artery disease (CAD) with history of myocardial infarct, history of coronary artery bypass grafting (CABG) mild ascending aorta dilation, history of Non-ST-Elevation Myocardial Infarction (NSTEMI), congestive heart failure (CHF) with cardiomyopathy, history of pulmonary embolism (PE), vitamin D deficiency, secondary hyperaldosteronism, secondary hyperparathyroidism, GERD, drug induced constipation, CKD stage 4, chronic pain syndrome, restless leg syndrome, paraparesis, neuromyopathy, obstructive sleep apnea (OSA), iron deficiency, and septic shock.

8. The third-party appeal review is dated January 3, 2024 and was completed by Richard Kalish, MD, MPH, MS, Medical Director, Elder Service Plan of Harbor Health. The decision to deny the request was based on a determination that the Barostim procedure is still experimental and undergoing longer term trials; Appellant does not qualify for the procedure from a clinical standpoint since his NT-proBNP has been greater than 1600 pg/ml 8 out of 10 times in 2023, including a value of 3109 pg/ml on 10/5/2023 and Barostim specifies that the value should be less than 1600 pg/ml; and there are substantial risks associated with the procedure.

9. The CHA PACE enrollment agreement specifies that experimental medical surgical or other health treatments are not covered by CHA PACE and are precluded from coverage by Medicare and MassHealth regulations.

10. The manufacturer of the Barostim Neo System states "[t]he BAROSTIM NEO System is indicated for the improvement of symptoms of heart failure—quality of life, six-minute hall walk and functional status—for patients who remain symptomatic despite treatment with guideline-directed medical therapy, are NYHA Class III or Class II (who had a recent history of Class III), have a left ventricular ejection fraction ≤ 35%, a NT-proBNP < 1600 pg/ml."

11. The Barostim Neo System is a specific BAT device that received FDA approval on August 16, 2019. The FDA approval requires Barostim to continue to trial the device for safety and long-term effects.

12. The Barostim Neo System is currently in clinical trials.

13. The Barostim Neo System's company website states "CAUTION: Investigational device. Limited by Federal Law (or United States) law to investigational use."

14. An article published by The American College of Cardiology on December 2, 2022, states that "given that the currently available evidence is insufficient to derive conclusion regarding reduction in mortality of hospitalization for HF with BAT, the contemporary European and American HF guidelines do not provide specific recommendations regarding the use of BAT in patients with HF."

15. An article, "Novel Non-pharmaceutical Advancements in Heart Failure Management: The Emerging Role of Technology" accepted to Current Cardiology Reviews in April of 2021 notes the: "Barostim Neo System is currently approved for use in Europe and recently received pre-market FDA approval in the U.S. A preliminary study has a 59% probability of being cost-effective, but further information is needed."

16. Regency Insurance Company has determined that there is currently not enough evidence to support the use of baroreflex stimulation devices. Regency included in its Medial Policy Manual "[t]here is not enough evidence to determine the overall impact of baroreflex stimulation devices for the treatment of any condition. Therefore, use of baroreflex stimulation is considered investigational for all indications, including but not limited to resistant hypertension and heart failure.

17. Blue Cross Blue Shield of Massachusetts lists baroreflex stimulation devices as investigational; and their policy notes "the evidence is insufficient to determine that the technology results in an improvement in the net health outcome."

18. Appellant's NT-proBNP measurements have exceeded 1600 pg/ml in the last year.

19. There are surgical risks associated with the BAT procedure.

20. Portsmouth, NH is outside the CHA PACE service area. CHA PACE generally authorizes out of area care in emergency situations, and only when a participant cannot return to the service area to receive care.

21. The requested BAT procedure is not available within the CHA PACE network, including its

contracted tertiary hospital, Beth Israel Deaconess Medical Center. While the Boston area includes several tertiary hospitals that are not contracted, CHA PACE will often approve procedures within the Boston area hospitals because of their close proximity to CHA PACE.

22. CHA PACE does not authorize care at hospitals outside of Boston or the Boston metro area because of the challenges related to coordinating care at such great distances from the PACE service area given the complexity and frailty of CHA PACE participants and the need to coordinate follow-up care.

23. Dr. LaMuraglia is a cardiologist at MGH not contracted with CHA PACE, who provided a recommendation for the procedure.

24. Dr. Lana Tsao, a cardiologist at MGH, recommended the BAT procedure for Appellant. Dr. Tsao is not contracted with CHA PACE.

25. Some insurance companies are partially paying for the BAT procedure and billing patients for the balance.

26. The CHA PACE cardiologist determined that the BAT procedure is not the standard of care and is not part of any of the American College of Cardiology algorithms or professional guidelines.

Analysis and Conclusions of Law

The party appealing an administrative decision bears the burden of demonstrating the decision's invalidity. Merisme v. Board of Appeals of Motor Vehicle Liability Policies and Bonds, 27 Mass. App. Ct. 470, 474 (1989).

The PACE program is a comprehensive health program that is designed to keep frail, older individuals who are certified eligible for nursing-facility services living in the community. A complete range of health-care services is provided by one designated community-based program with all medical and social services coordinated by a team of health professionals. The MassHealth agency administers the program in Massachusetts as the Elder Service Plan (ESP). Persons enrolled in PACE have services delivered through managed care in day-health centers; at home; and in specialty or inpatient settings, if needed (130 CMR 519.007(C)).[4]

[4] See 42 CFR § 460.90 PACE benefits under Medicare and Medicaid. If a Medicare beneficiary or Medicaid beneficiary chooses to enroll in a PACE program, the following conditions apply: (a) Medicare and Medicaid benefit limitations and conditions relating to amount, duration, scope of services, deductibles, copayments, coinsurance, or other cost-sharing do not apply. (b) The participant, while enrolled in a PACE program, must receive Medicare and Medicaid benefits solely through the PACE organization.
See also 42 CFR § 460.92 Required services. (a) The PACE benefit package for all participants, regardless of the source of payment, must include the following: (1) All Medicare-covered services. (2) All Medicaid-covered services, as specified in

Regulation 130 CMR 450.204: Medical Necessity states:

> The MassHealth agency does not pay a provider for services that are not medically necessary and may impose sanctions on a provider for providing or prescribing a service or for admitting a member to an inpatient facility where such service or admission is not medically necessary.
>
> (A) A service is medically necessary if
>
> (1) it is reasonably calculated to prevent, diagnose, prevent the worsening of, alleviate, correct, or cure conditions in the member that endanger life, cause suffering or pain, cause physical deformity or malfunction, threaten to cause or to aggravate a handicap, or result in illness or infirmity; and
>
> (2) there is no other medical service or site of service, comparable in effect, available, and suitable for the member requesting the service, that is more conservative or less costly to the MassHealth agency. Services that are less costly to the MassHealth agency include, but are not limited to, health care reasonably known by the provider, or identified by the MassHealth agency pursuant to a prior-authorization request, to be available to the member through sources described in 130 CMR 450.317(C), 503.007: *Potential Sources of Health Care*, or 517.007: *Utilization of Potential Benefits*.
>
> (B) Medically necessary services must be of a quality that meets professionally recognized standards of health care, and must be substantiated by records including evidence of such medical necessity and quality. A provider must make those records, including medical records, available to the MassHealth agency upon request. (*See* 42 U.S.C. 1396a(a)(30) and 42 CFR 440.230 and 440.260.)
>
> (C) A provider's opinion or clinical determination that a service is not medically necessary does not constitute an action by the MassHealth agency.
>
> (D) Additional requirements about the medical necessity of MassHealth services are contained in other MassHealth regulations and medical necessity and coverage guidelines.
>
> **(E) Any regulatory or contractual exclusion from payment of experimental or unproven services refers to any service for which there is insufficient authoritative**

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the State's approved Medicaid plan. (3) Other services determined necessary by the interdisciplinary team to improve and maintain the participant's overall health status. (b) Decisions by the interdisciplinary team to provide or deny services under paragraph (a) of this section must be based on an evaluation of the participant that takes into account: (1) The participant's current medical, physical, emotional, and social needs; and (2) Current clinical practice guidelines and professional standards of care applicable to the particular service.

evidence that such service is reasonably calculated to have the effect described in 130 CMR 450.204(A)(1).[5] (Emphasis added)

By notice dated January 10, 2024, and following a denial of an internal appeal issued on December 12, 2023, CHA PACE informed Appellant that his request for coverage for a non-emergent Barostim implantation procedure at Portsmouth Regional Hospital was denied because the Interdisciplinary Team determined, in conjunction with an independent third-party reviewer, that the Barostim device requested is still experimental and undergoing longer term trials. First, there is no evidence to corroborate Appellant's testimony that the requested procedure was approved by CHA PACE. Although Drs. LaMuraglia and Tsao are cardiologists at MGH, and recommended the procedure for Appellant, neither cardiologist is contracted with CHA PACE, and neither had the authority to make decisions on behalf of the CHA PACE Interdisciplinary Team. There is nothing in the hearing record that can be construed as a CHA PACE approval of the service requested, and the CHA PACE representatives credibly dispelled Appellant's assertion that the service requested had been previously approved.

Next, a preponderance of the evidence and testimony supports the conclusion that the Barostim Neo System device requested is correctly characterized as experimental and that CHA PACE correctly denied the requested service for this reason. While Appellant testified to a list of other insurance companies that have approved coverage for the requested device, there is no corresponding evidence of the portions paid by the insurer and by patients as CHA PACE testified, and there is no additional narrative provided by any of the companies listed that shows that the service requested is not experimental.[6] In terms of evidentiary weight, a list of companies approving the service without additional narrative or testimony showing why a particular company approved the service does not demonstrate medical necessity within the regulatory parameters applicable to CHA PACE. In comparison, CHA PACE submitted narrative and rationale from two insurers that articulated their rationale for non-coverage, with Regency including in its Medial Policy Manual "[t]here is not enough evidence to determine the overall impact of baroreflex stimulation devices for the treatment of any condition. Therefore, use of baroreflex stimulation is considered investigational for all indications, including but not limited to resistant hypertension and heart failure (Exhibit 4., pp. 88-89). In addition, Blue Cross Blue Shield of Massachusetts also lists baroreflex stimulation devices as investigational; and their policy states "the evidence is insufficient to determine that the technology results in an improvement in the net health outcome" (Id., p. 94). While neither insurance company's position is dispositive on the issue of medical necessity, the CHA PACE evidence is given more weight in deciding the issue at hand.

Further, consideration of the articles submitted by both parties weighs in favor of the CHA PACE position that the Barostim Neo System is experimental at this time, and therefore is a non-covered

[5] See also 42 CFR 460.96 which excludes from coverage under PACE (b) Experimental medical, surgical, or other health procedures, and Exhibit 4, p. 15.

[6] See Exhibit 2, p 14: Letter from Dr. Wilson listing insurance companies purportedly approving the procedure.

service.[7] Dr. Burns testified credibly that he reviewed the materials submitted by Appellant which did not change his medical opinion that the Barostim Neo System is experimental at this time, which is further corroborated by the third-party independent reviewer Dr. Richard Kalish, MD, MPH, MS, Medical Director, Elder Service Plan of Harbor Health who concluded that the Barostim procedure is still experimental and undergoing longer term trials (Exhibit 4, p. 13).[8] Additional evidence for this conclusion is found on the Barostim Neo System's company website which acknowledges the product's investigational status, and the FDA approval which requires additional studies (Id, pp. 20-24). Therefore, I conclude that Appellant has not carried the burden of proof in showing that the Barostim Neo System device and implant procedure meets medically necessity criteria as defined at 130 CMR 450.204.

Analysis of the secondary issue which is based on manufacturer specifications is somewhat obviated by the above determination. However, this hearing officer defers to the CHA PACE clinical determination that because Appellant's NT-proBNP measurements have exceeded manufacturer specifications of 1600 pg/ml, 8 times between 1/11/2023 and 2/21/2024, clinical criteria are not met.[9]

On the CHA PACE determination to deny the procedure because the Portsmouth, NH hospital and provider are outside of the CHA PACE service area, care is generally only authorized outside the service area in emergency situations, and only when a participant cannot return to the service area to receive care (Exhibit 4, p. 14).[10,11] The CHA PACE representatives testified credibly that the

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[7] See and compare Findings of Fact 14 and 15 with Appellant's articles: "Baroreflex Activation Therapy in Patients With Heart Failure With Reduced Ejection Fraction, which concludes that in certain patients BAT is safe, but also identifies in Trial Limitations and Future Directions that additional studies are needed in the post-market phase, and that further studies are needed to assess the impact of BAT on the frequency of hospitalization and mortality, and to identify patients with HFrEF most likely to gain lasting benefit from this type of intervention (Exhibit 2, p. 40); Appellant's Product Brief: "Barostim Neo System (CRVx, Inc.) for Treating Heart Failure," which concludes "Preliminary evidence (6-months results) from 2 ongoing randomized controlled trials (RCTs) shows that Barostim Neo is safe and more effective than optimal medical therapy (OMT) for improving quality of life (QOL) and functional status in patients with chronic HF with left ventricular ejection fraction (LVEF) less than or equal to 35%. However, results need validation in additional independent RCTs comparing Barostim Neo with OMT and reporting longer-term data" (Id., 42-49); Appellant's article "Barostim NEO-Baroreflex Activation Therapy for the Treatment of Systolic Heart Failure" which provides a brief overview of the positive findings of various studies, but not the underlying studies (Id., pp. 16-18); and the Summary of Safety and Effectiveness DATA (SSED) which presents in one page, indications for use and contraindications and does not speak beyond its stated conclusions (Id., p. 19).

[8] See also Exhibit 4, p. 54-68 for Study Details, Baroreflex Activation Therapy for Heart Failure.

[9] See NT-proBNP test results, Exhibit 4, pp. 105-117, and Id., p. 3.

[10] See also 42 CFR 460.98, 460.100.

[11] See Exhibit 4, p. 10: Requirements for PACE program enrollment agreements are outlined at 42 CFR 460.154. The CHA PACE enrollment agreement states "[t]he services offered by CHA PACE are available to you because of a special agreement between CHA PACE, the Commonwealth of Massachusetts, MassHealth and the U.S. Department of Health & Human Services (CMS). Once you have enrolled in CHA PACE, you agree to receive services exclusively from CHA PACE providers and CHA PACE contracted providers. You will be fully and personally liable for the costs of unauthorized and/or out of network services. You will no longer be able to obtain services from other doctors or medical providers under your previous coverage (i.e. original Medicare and MassHealth

requested procedure is not available within the CHA PACE network, including its contracted tertiary hospital, Beth Israel Deaconess Medical Center, and that CHA PACE does not authorize care at hospitals outside of Boston or the Boston metro area because of the challenges related to coordinating care at such great distances from the PACE service area given the complexity and frailty of CHA PACE participants and the need to coordinate follow-up care.

For the foregoing reasons, the appeal is DENIED.

Order for CHA PACE

None.

Notification of Your Right to Appeal to Court

If you disagree with this decision, you have the right to appeal to Court in accordance with Chapter 30A of the Massachusetts General Laws. To appeal, you must file a complaint with the Superior Court for the county where you reside, or Suffolk County Superior Court, within 30 days of your receipt of this decision.

Thomas J. Goode
Hearing Officer
Board of Hearings

cc:
Cambridge Health Alliance, Attn: Kathryn Tylander, PT, DPT, Manager of Quality and Compliance, 163 Gore Street, Cambridge, MA 02141

providers.