



February 8, 2019

Larry Chan
HAPG – Division of Practitioner Services (DPS)
Centers for Medicare & Medicaid Services
C4-04-27
7500 Security Blvd
Baltimore, MD 21224
(410) 786-6864
Larry.Chan@cms.hhs.gov

RE: Medicare Program; Revisions to Payment Policies Under the Physician Fee Schedule and Other Revisions to Part B for CY 2019; Medicare Shared Savings Program Requirements; Quality Payment Program; and Medicaid Promoting Interoperability Program

Dear Mr. Chan,

On behalf of Legacy Heart Care, LLC (Legacy), I write to respectfully request immediate action to revise HCPCS code G0166 that was inappropriately revalued in the CY 2019 Physician Fee Schedule (PFS) Final Rule. If left unaddressed, this action will significantly impede Legacy's ability to continue providing this life-enhancing treatment to our patients. We appreciate the opportunity to bring this matter to your attention.

Legacy is the nation's leading healthcare provider for the non-invasive cardiovascular therapy External Counterpulsation (ECP; HCPCS Code G0166), delivering an estimated 25% of the national utilization for this service. Per the Purpose Statement to our organization, we firmly believe in making a positive impact on every life we touch and have been achieving this objective for the past 15 years. We have a unique expertise on this particular service and proudly partner with over 1,000 cardiologists (many members of American College of Cardiology) in the communities we serve to deliver exemplary health care to Medicare beneficiaries.

In opening, I would like to point out the reason of the timing of this correspondence. The Federal Register for the PFS Proposed Rule (83 FR 35704)¹ did not correspond with the changes made in the fee schedule formula, more specifically the PE RVU inputs. In

reviewing the Proposed Rule, we hope you will agree with the confusion when reconciling the facts listed in this document compared to the actual changes to Code G0166.

There are 4 items I would like to point to in this document:

1. Proposed Valuation of Specific Codes: (62) External Counterpulsation (HCPCS CODE G0166) *83 FR 35772*
2. Table 13 – CY2019 Proposed Work RVUs for New, Revised, and Potentially Misvalued Codes *83 FR 35786*
3. Table 14 – CY2019 Proposed Direct PE Refinements *83 FR 35787*
4. Table 17 – Proposed CY2019 No Direct PE Refinements *83 FR 35832*

In the Proposed Valuation section, the rule text clearly states there is a proposed adjustment to work RVU. In the last sentence, the proposal suggests PE RVU refinement to the equipment times in accordance to standard equipment time formulas. This is the only textual reference to adjustment of PE RVU inputs.

In Table 13, G0166 is listed in agreement to the Proposed Valuation section that the work RVU will be adjusted from 0.07 to 0.00. Legacy Heart Care reviewed this suggestion and did not contest.

In Table 14, titled Proposed Direct PE Refinements, G0166 **is not** listed.

In Table 17, titled **No** Direct PE Refinements, G0166 **is** listed.

We reviewed this information in July 2018 and elected not to comment because we agreed with the information provided in the ruling. However, we were certainly caught off guard when discovering significant changes were made to several components of the PE RVU inputs that resulted in a 20% reduction for G0166. We understand that CMS promotes an environment of transparency and values high-quality care for its beneficiaries, so we appreciate the opportunity to clarify facts that we believe will compel the Agency to revise accordingly the direct PE inputs for this value-added service. Unfortunately, if G0166 is not adjusted back to CY 2018 rates, we are concerned that our ability to continue providing these life-enhancing treatments to Medicare beneficiaries whom greatly benefit from our services will be significantly impeded and force patients to utilize higher cost services, such as emergency services.

The Legacy Heart Care Approach

Legacy Heart Care develops and manages focused cardiovascular treatment facilities that specialize in ECP. The Legacy Heart Care clinics are currently the largest provider of ECP services in the United States and have been nationally recognized as the leader in quality. Legacy Heart

Care earned this distinction by completely rethinking the treatment experience from both a clinical and patient-centered perspective.

There is recognition that, historically, the modality of treatment may have limited the broad utilization of ECP. Legacy Heart Care advocates that this bias is not associated with the clinical aspects of the therapy but rather stems from non-clinical challenges associated with the delivery of ECP in traditional settings. Such challenges are as follows:

The overwhelming majority of ECP treatment has been provided via a single unit within the infrastructure of a cardiovascular group practice or hospital setting. Under this model, viable patient volumes are rarely achieved within the group and non-group referrals are the exception. There is a strong tendency against referring patients to a competing practice for a 7-week treatment regime. This lack of sustainable volume, along with the compromised patient experience, is a natural deterrent for a single group or hospital to focus on ECP and for patients to complete the full course of treatment.

For the past 15 years, Legacy Heart Care has removed the therapy from its typical confines of a single bed in a single exam-room, designing 8-10 treatment unit facilities that are easily accessible to the broad healthcare communities we serve. Legacy Heart Care consciously designed the treatment experience and operational flow down the smallest of details, resulting in high levels of patient compliance with and completion of treatment. In fact, while the national completion rate with the historical model averaged 60%, over 90% of patients initiating treatment at Legacy Heart Care will complete their entire seven-week course of therapy. This is a significant advancement to the historical challenges this therapy faced in previous single-bed-models that may devote a single technician.

As an example, with the standard course of ECP at Legacy's facility, a cardiovascular nurse practitioner, will be dedicated to the patient's 7-week course (one hour a day, five days a week). At each visit the patient is weighed, vital signs are taken pre and post treatment, and EKG is continuously monitored throughout the treatment. The nurse practitioner auscultates heart and lung sounds, assesses volume status, reviews medication adherence, educates for co-morbidities and chronic conditions, discusses nutrition and activity levels, and acts as a conduit to the patient's community physicians if the patient is showing any significant change in status. This focus on education and patient care has been proven to reduce hospital readmissions. Our work was published in the *American Journal of Cardiology* demonstrating an 82% reduction in 90-day hospital readmissions (34% to 6%).² Many do not recognize that ECP has over 400 published peer reviewed articles and 13 randomized control trials proving its safety and efficacy.[Attachment 3]

The Legacy Heart Care clinics have redefined the delivery system of this technology, developing a dynamic program with ECP at its core. Data collected on Legacy Heart Care patients – pre-

treatment, over the course of treatment, and post-treatment (up to 2 year follow up) – provides a strong evidentiary basis for the value of this therapy. [Attachment 2] Improvements in symptom frequency and severity, enhanced quality of life measures, and a reduction in health care resource utilization place Legacy Heart Care in the center of the Triple Aim initiative. Along with our clinical outcome measures, Legacy has earned a Net Promotor Score (NPS) of 88 from our patients.

Our overriding concern is that CMS is unaware of the full set of facts that have led to the recent changes in RVU inputs, which will result in our program disappearing for all stakeholders – the patients and CMS. Therefore, we respectfully request that the information that was used to make the changes in Labor Code value from 0.51 for a registered nurse to 0.37 for a technician/limited practice nurse blend. As mentioned above, Legacy is viewed as a Center of Excellence for these chronic ischemic patients, our centers can offer care to 25-45 patients per day and service an entire community for this specialized service.

In our staffing model, we dedicate a Nurse Practitioner to every 4-5 patients per hour (simultaneously being treated, similar to a dialysis center model). In addition, we have 1 Medical Technician for every 2 patients per hour. We have learned over 15 years of experience that it is necessary to dedicate this licensed provider along with the described medical technician ratio, who are supervised by a physician, in order to deliver appropriate care for these complex patients. Many of our patients have 4-6 chronic conditions that our staff can assist managing through the 35 treatment sessions. Not only are our Nurse Practitioners essential to coaching patients to adhere to their treatment programs (90% adherence vs 60%), this dedicated oversight adds tremendous value by advancing patient self-management skills.

Although we are not requesting an increase to the RVU labor inputs from years past or challenging the work RVU adjustment described in the CY 2019 Final Rule, we certainly do not believe it is indicative or practical use to reduce the labor code from 0.51 to 0.37. We believe it is relevant the CMS decided the Labor Code value 0.51 for the past 15 years. It appears there has not been an appropriate review to conclude of any such change.

In addition, we would like to contest the accuracy of the contractor (StrategyGen) CMS utilized for equipment pricing. Please see the attached [Attachment 1] 5-year pricing from Vasomedical, which is the only manufacturer of ECP equipment with proven randomized control trials (RCT) to support meaningful clinical outcomes. StrategyGen has recommended a change in equipment cost from \$150,000 to roughly \$61,000 over a 4-year phase-in for EQ012 (ECP equipment). This change is exceptionally misrepresentative and would be detrimental to the ability to offer care to Medicare beneficiaries if it affected the PE RVU inputs. It is clear that the contractor most likely did not have access to complete information, such as, the understanding of the cost of equipment from the only manufacturer the with RCT clinical outcomes, the cost of preventative maintenance, expensive parts that degrade within one year (treatment hoses, treatment cuffs,

valves, carbon fins on air compressors, air regulators, treatment bladders, and ECG cables). All of these elements are part of the Equipment costs that need to be taken into account.

Additionally, we believe the Practice Expense Subcommittee erred because it did not have certain information to include all the necessary information in regard to the Supply vignette to CMS. Notes state the patient is fully clothed during treatment – this is untrue. ECP must be performed with a patient in specialized treatment pants. These pants fit to the legs to prevent blistering and do not impede the appropriate compression that is the foundation of the therapy. If a patient wore clothing such as pants or shorts, the therapy would be ineffective or dangerous. This is yet another example of RVU inputs being altered without the full set of facts.

Legacy is devoted to making a difference through value to Medicare beneficiaries. We work directly with patients that have multiple chronic conditions and have the ability to deliver care for 35 consecutive days with a 90% completion rate. We specialize in keeping patients out of the hospital and continue to generate compelling data that saves the system significant resources and drives health to your beneficiaries [Attachment 2]. Therefore, we urge CMS to fully consider all pertinent facts before assuming the historical delivery of ECP is the only method of success with this technology. Below is a list of some of the leading hospital system's we partner with to provide care to their patients:

Baylor Scott & White
Texas Health Resources
UT Southwestern
Veterans Administration
Methodist Healthcare System
Hospital Corporation of America
Adventist Health System
St. David's (HCA)
Seton Medical Center (Ascension)
Atrium Health
Novant Health
Banner Health
Dignity Health
HonorHealth
Tenet Healthcare
Caromont Health
Piedmont Medical Center
University Health System
Baptist Health System

Specifically, we request that a technical correction—to revise the equipment and clinical staff direct practice expense inputs discussed above—be retroactively implemented as soon as possible, hopefully in a quarterly update in 2019. The RUC reviewed this service for CY 2019 rulemaking and we do not believe further review by that group will improve the accuracy of the inputs beyond the information provided in this document.

Given the time-sensitive urgency of this matter, I welcome the opportunity to speak with you directly to address any questions and clarify any concerns you may have. I will be reaching out to you shortly to schedule a time for us to meet in person and thank you for your prompt attention to this matter.

Sincerely,



Michael Gratch
Legacy Heart Care President

cc: Seema Verma, Administrator
Demetrios Kouzoukas, Principal Deputy Administrator for Medicare and Director, Center for Medicare
Elizabeth Richter, Deputy Director, Center for Medicare
Carol Blackford, Director, Hospital and Ambulatory Policy Group, Center for Medicare
Ing-Jye Cheng, Deputy Director, Hospital and Ambulatory Policy Group, Center for Medicare
Edith Hambrick, Hospital and Ambulatory Policy Group, Center for Medicare

ATTACHMENTS

1. Vasomedical Program Cost Analysis
2. LHC Outcomes
3. Bibliography of PubMed indexed articles on external counterpulsation (ECP) or EECP

REFERENCES

1. Office of the Federal Register. Medicare Program; Revisions to Payment Policies Under the Physician Fee Schedule and Other Revisions to Part B for CY 2019; Medicare Shared Savings Program Requirements; Quality Payment Program; and Medicaid Promoting Interoperability Program. Available from: <https://www.federalregister.gov/d/2018-14985/> [Accessed 06 February 2019]
2. Tecson KM, Silver MA, Brune SD et al. Impact of Enhanced External Counterpulsation on Heart Failure Rehospitalization in Patients With Ischemic Cardiomyopathy. Am J Cardiol. 2016 Mar 15;117(6):901-5.



Estimated Cost Analysis for EECF System, Accessories and Services

This 5-year estimated cost analysis for EECF system, accessories and services is based on 4 patients per day, 5 days a week @ 260 working days per year

1,040 = Treatment Hours for 1 Year for 1 Lumenair
30 = Estimated Patients Per Year = (1,040 standard hours / 35 treatment hours per patient)

	Year 1		Year 2		Year 3		Year 4		Year 5		Total	
	Quantity	Cost	Quantity	Cost	Quantity	Cost	Quantity	Cost	Quantity	Cost	Quantity	Cost
Lumenair EECF System		\$19,000.00		\$19,000.00		\$19,000.00		\$19,000.00		\$19,000.00		\$95,000.00
Cuff Sets	9	\$1,980.00	2	\$440.00	6	\$1,320.00	6	\$1,320.00	6	\$1,320.00	29	\$6,380.00
Connectors	54	\$243.00	0	\$0.00	0	\$0.00	6	\$27.00	6	\$27.00	66	\$297.00
Bladder Sets	9	\$585.00	2	\$130.00	6	\$390.00	6	\$390.00	6	\$390.00	29	\$1,885.00
Treatment Pants	29	\$507.50	33	\$577.50	33	\$577.50	33	\$577.50	33	\$577.50	161	\$2,817.50
ECG Paper	2	\$22.00	4	\$44.00	4	\$44.00	4	\$44.00	4	\$44.00	18	\$198.00
Nu Prep Gel, 4 oz (3 pak)	2	\$72.00	1	\$36.00	1	\$36.00	2	\$72.00	1	\$36.00	7	\$252.00
3 Lead ECG Cable	0	\$0.00	1	\$140.00	1	\$140.00	1	\$140.00	1	\$140.00	4	\$560.00
Electrodes (600 per case)	5	\$910.00	5	\$910.00	5	\$910.00	5	\$910.00	5	\$910.00	25	\$4,550.00
Hoses	0	\$0.00	0	\$0.00	1	\$360.00	1	\$360.00	1	\$360.00	3	\$1,080.00
SpO2 Probe	0	\$0.00	0	\$0.00	1	\$252.00	0	\$0.00	1	\$252.00	2	\$504.00
Patient Stop Cable	0	\$0.00	0	\$0.00	0	\$0.00	1	\$300.00	0	\$0.00	1	\$300.00
Service / Maintenance	0	\$0.00	1	\$8,995.00	1	\$8,995.00	1	\$8,995.00	1	\$8,995.00	4	\$35,980.00
Clinical Training	0	\$0.00	0	\$0.00	1	\$4,500.00	0	\$0.00	1	\$4,500.00	2	\$9,000.00
TOTAL		\$23,319.50		\$30,772.50		\$36,524.50		\$32,135.50		\$36,551.50		\$158,803.50
Cost per patient		\$777.32		\$1,009.08		\$1,217.48		\$1,071.18		\$1,218.38		\$1,058.69

Total estimated cost for Vasomedical related products and services for a 5-year EECF Program.

\$158,803.50

Average cost per patient per year **\$1,058.69**

This estimate does not take into account other costs associated with administering an EECF program, such as space, staff, marketing, supplies other incidentals.

DISCLAIMER:
This analysis is provided only as a general estimate. Results depend on many factors. Vasomedical does not make any representation as to its accuracy or applicability to one's particular circumstances.
This analysis is not an offer, representation or warranty by Vasomedical. The specific values shown in these calculations may not be the values of any offers made by Vasomedical at any time. Any product or service purchase from Vasomedical will be governed exclusively by the terms of the specific written agreement based on that product or service.



137 Commercial St., Unit 200, Plainville, NY 11803 USA Tel: 800-455-3227 +1 516-997-4600 Fax: +1 516-997-2299 customerservice@vasosolutions.com www.vasosolutions.com

EECP® THERAPY CONSUMABLES/ACCESSORIES ORDER FORM

Facility Name: _____ Customer ID No.: _____ Purchase Order No.: _____

Address: _____ City: _____ State: _____ Zip: _____

Ship to Attn: _____ Phone: _____ Fax: _____ E Mail: _____

Shipping Method (Select one): ☐ Next Day AM ☐ Next Day ☐ 2nd Day ☐ 3rd Day ☐ Ground (Customer is responsible for all shipping charges)

Place Orders via fax: (516) 997-6971 or E Mail: ehara@vasomedical.com

QTY	P/N	DESCRIPTION	PRICE
	V93-0003	Z-Fold ECG Paper, 147 ft. (Models TS3, and TS4 and Lumenair™)	\$11.00
	2-128	Roll ECG Paper, 240 ft. (Model MC2)	\$8.00
	V93-0025-1	Nu Prep Gel, 4 oz (3 Pk)	\$36.00
	V93-0026	Signa Electrode Gel, 8 oz	\$8.50
	V93-0026-1	Signa Electrode Gel, 2 oz	\$4.75
	A12-0033	3 Lead Integrated ECG Cable (AngioNew® V & VI)	\$450.00
	V10-0017	3 Lead Integrated ECG Cable (Models MC2, TS4 and Lumenair™)	\$140.00
	V10-0021	3 Lead Integrated ECG Cable (Model TS3—including adapter)	\$175.00
	V83-0066	ECG Cable Adaptor (Model TS3 – for use with V10-0017)	\$65.00
	V93-0020	Electrodes (600 per case)	\$182.00
	V23-0005	Cuff Set, X-Small	\$220.00
	V23-0004	Cuff Set, Small	\$220.00
	V23-0003	Cuff Set, Medium	\$220.00
	V23-0002	Cuff Set, Large	\$220.00
	V23-0001	Cuff Set, X-Large	\$220.00
	V23-0077	Cuff Set, XX-Large	\$220.00
	V10-0022-1	Thigh Cuff, X-Small	\$170.00
	V10-0022-2	Thigh Cuff, Small	\$170.00
	V10-0022-3	Thigh Cuff, Medium	\$170.00
	V10-0022-4	Thigh Cuff, Large	\$170.00
	V10-0022-5	Thigh Cuff, X-Large	\$170.00
	V10-0022-6	Thigh Cuff, XX-Large	\$170.00
	V10-0023-1	Calf Cuff, X-Small	\$75.00
	V10-0023-2	Calf Cuff, Small, Medium & Large	\$75.00
	V10-0023-5	Calf Cuff, X-Large	\$75.00
	V10-0023-6	Calf Cuff, XX-Large	\$75.00
	V23-0013	Bladder Set, X-Small	\$65.00
	V23-0012	Bladder Set, Small	\$65.00
	V23-0011	Bladder Set, Medium	\$65.00
	V23-0010	Bladder Set, Large	\$65.00
	V23-0000	Bladder Set, X-Large (should be used with XL and XXL cuffs)	\$65.00

QTY	P/N	DESCRIPTION	PRICE
	V23-0022-1	Treatment Pants, X-Small	\$17.50
	V23-0022-2	Treatment Pants, Small	\$17.50
	V23-0022-3	Treatment Pants, Medium	\$17.50
	V23-0022-4	Treatment Pants, Large	\$17.50
	V23-0022-5	Treatment Pants, X-Large	\$17.50
	V23-0022-6	Treatment Pants, XX-Large	\$17.50
	V10-0011	Finger Plethysmograph (Models TS3 and TS4)	\$325.00
	V83-0006	Finger Plethysmograph (Model MC2, AngioNew® V & VI)	\$168.00
	V23-0007	Abdominal Extension Strap	\$20.00
	V23-0006	Ankle Strap	\$30.00
	V31-0267	Twilok™ Cuff Side Hose Connector	\$4.50
	V53-0084	Twilok™ System Adapter for Hose (inserted into system table)	\$2.25
	V23-0075-0	Hose, Set of 6 (Lumenair™)	\$360.00
	V23-0078-0	Hose, Set of 6 (Models MC2, TS3, TS4)	\$360.00
	V53-0087-0	Hose, Single, (Models MC2, TS3, TS4 and Lumenair for Lower Thigh And Calf)	\$65.00
	V53-0086-0	Hose, Single, Upper Thigh (Lumenair™)	\$65.00
	A12-0047	Hose, Complete Set, Calif, Upper Thigh & Lower Thigh (AngioNew® V)	\$1,125.00
	A12-0045-0	Hose Single, (250mm) (AngioNew® VI)	\$72.00
	A12-0044-0	Hose Single, (300mm) (AngioNew® VI)	\$72.00
	A12-0046-0	Hose, Set of 6 (AngioNew® VI)	\$550.00
	V83-0253	Spo2 Probe (Lumenair™ and Model TS4)	\$252.00
	A12-0035	Spo2 Probe (Older AngioNew® V and VI)	\$380.00
	A12-0037	Spo2 Probe (Newer AngioNew® V and VI)	\$380.00
	V10-0012	Patient Stop Cable (Model TS3)	\$300.00
	V10-0014	Patient Stop Cable (Model TS4 and Lumenair™)	\$300.00
	A12-0036	Patient Stop Cable (AngioNew® V and VI)	\$200.00

Additional Notes:

*Prices subject to change. EECP is a registered trademark of Vasomedical, Inc. All rights reserved.

SER/0100-10 Rev.8 (Effective 2/29/2016)

IMPACT OF ENHANCED EXTERNAL COUNTERPULSATION ON HEART FAILURE REHOSPITALIZATION AMONG PATIENTS WITH ISCHEMIC CARDIOMYOPATHY

American Journal of Cardiology, Vol. 117, No. 6, 15.03.2016, p. 901-905.

Tecson, Kristen M.; Silver, Marc A.; Brune, Sonja D.; Cauthen, Clay; Kwan, Michael D.; Schussler, Jeffrey M.; Vasudevan, Anupama; Watts, James A.; McCullough, Peter A.

The
American Journal
of Cardiology

www.ajconline.org



Study Design

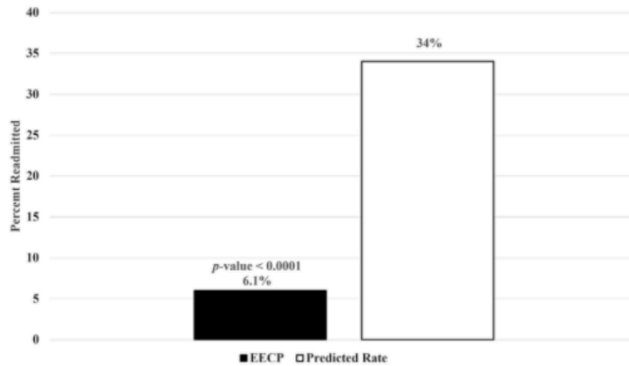
- Assess the potential for reduced readmission in post-acute care heart failure patients referred into an educational program and for EEC
- Examined 99 patients receiving EEC within 90 days of hospital discharge
- Compared observed and predicted 90 day rates of readmission, as well as six minute walk distances, DASI, NYHA, and CCS pre and post EEC
- All patients were enrolled in education and treatment at Legacy (Trinity) Heart Care clinics, specializing in EEC

Results

- Six (6.1%) unplanned readmissions within 90 days, versus a predicted rate of 34%. p-value < 0.0001
- Average six minute walk distance increased by 52 meters (18.4%), while DASI improved 9.95 points (100%). P-value < 0.0001
- NYHA and CCS improved by at least one class in 61% and 60% of patients respectively.

ABSTRACT





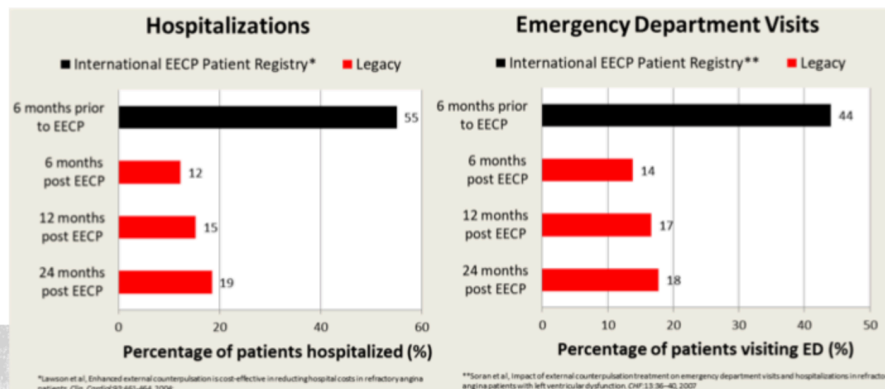
READMISSION RATES: OBSERVED VS. PREDICTED

American Journal of
Cardiology DOI:
(10.1016/j.amjcard.2015.12.0
24)

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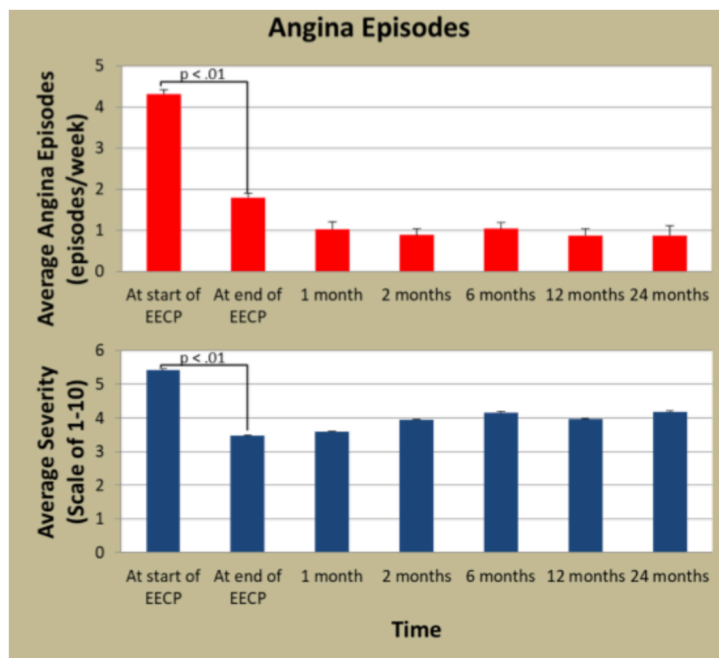


HEALTH CARE UTILIZATION



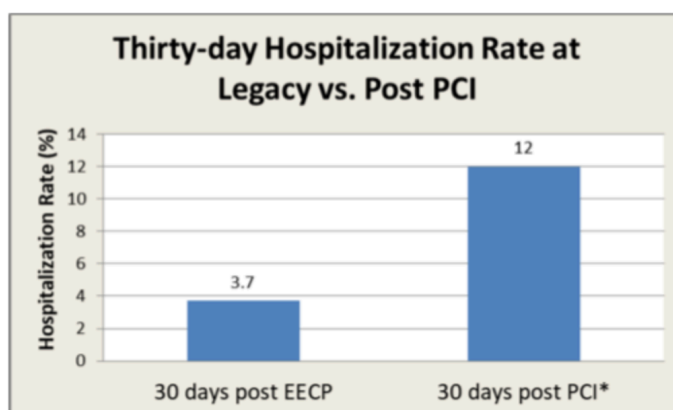
Data for 3717 patients treated with enhanced external counterpulsation (EECP) at Legacy Heart Care was analyzed over a two year period after treatment.





CHANGE IN ANGINA AT LEGACY

Data for 2291 patients treated with EECP at Legacy Heart Care was analyzed.

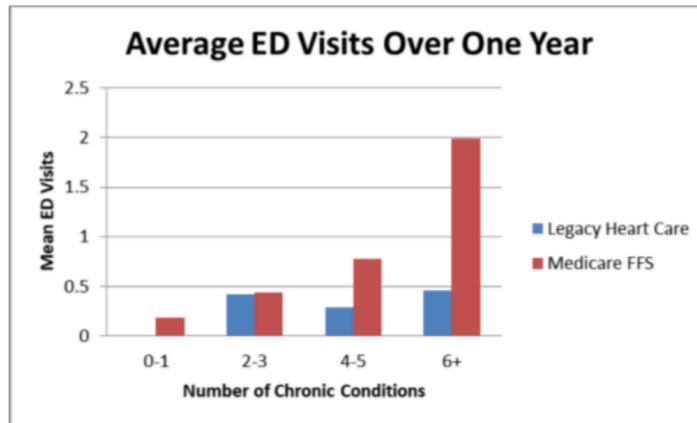


*Circ Cardiovasc Interv. 2017 Dec;10(12). pii: e005925. doi: 10.1161/CIRCINTERVENTIONS.117.005925.

HOSPITALIZATIONS POST EECP ARE MUCH LOWER THAN POST-PCI

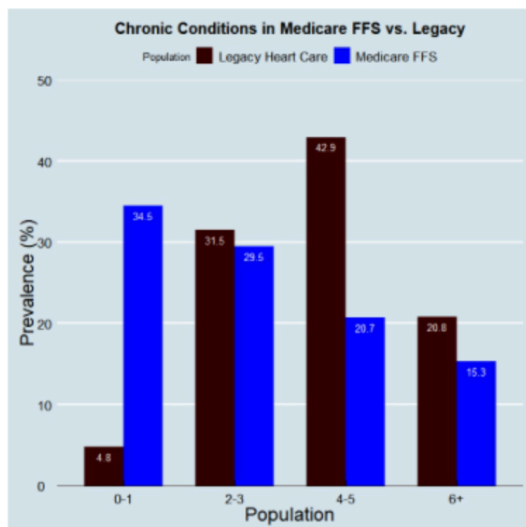
- Hospitalizations at 30 were much lower than the reported rate of 12% for post-PCI patients.
- Of those hospitalized during treatment, only 1.36% were hospitalized within 30 days of completing treatment at Legacy Heart Care.





ED VISITS COMPARED TO MEDICARE FFS

- Average ED Visits over the period of one year broken down by chronic condition categories.
- Patients treated at Legacy Heart Care had a much lower rate of ED Visits, especially for patients with 4 or more chronic conditions.



CHRONIC CONDITIONS COMPARED TO MEDICARE FFS PATIENTS

- When compared to the Medicare FFS population, Legacy Heart Care treats patients that on average have many more chronic conditions.
- Even when compared to the over 65 population, the population treated at Legacy Heart Care has many more chronic conditions.



Attachment 3

External Counterpulsation / EECp PUBMED INDEXED CITATIONS (N=421) [February 08, 2019]

- 1: Raeissadat SA, Javadi A, Allameh F. Enhanced external counterpulsation in rehabilitation of erectile dysfunction: a narrative literature review. *Vasc Health Risk Manag.* 2018 Dec 3;14:393-399. doi: 10.2147/VHRM.S181708. eCollection 2018. Review. PubMed PMID: 30584313; PubMed Central PMCID: PMC6284534.
- 2: Wu E, Broström A, Mårtensson J. Experiences of Undergoing Enhanced External Counterpulsation in Patients With Refractory Angina Pectoris: A Qualitative Study. *J Cardiovasc Nurs.* 2018 Sep 28. doi: 10.1097/JCN.0000000000000530. [Epub ahead of print] PubMed PMID: 30273260.
- 3: Abdelwahab AA, Elsaied AM. Can enhanced external counter pulsation as a non-invasive modality be useful in patients with ischemic cardiomyopathy after coronary artery bypass grafting? *Egypt Heart J.* 2018 Jun;70(2):119-123. doi: 10.1016/j.ehj.2018.01.002. Epub 2018 Feb 1. PubMed PMID: 30166893; PubMed Central PMCID: PMC6112334.
- 4: Sardari A, Hosseini SK, Bozorgi A, Lotfi-Tokaldany M, Sadeghian H, Nejatian M. Effects of Enhanced External Counterpulsation on Heart Rate Recovery in Patients with Coronary Artery Disease. *J Tehran Heart Cent.* 2018 Jan;13(1):13-17. PubMed PMID: 29997665; PubMed Central PMCID: PMC6037627.
- 5: Valenzuela PL, Montalvo Z, Torrontegi E, Sánchez-Martínez G, Lucia A, de la Villa P. Enhanced External Counterpulsation and Recovery From a Plyometric Exercise Bout. *Clin J Sport Med.* 2018 Jun 26. doi: 10.1097/JSM.0000000000000620. [Epub ahead of print] PubMed PMID: 29952839.
- 6: Buschmann EE, Hillmeister P, Bondke Persson A, Liebeskind DS, Schlich L, Kamenzky R, Busjahn A, Buschmann IR, Bramlage P, Hetzel A, Reinhard M. Short-term external counterpulsation augments cerebral blood flow and tissue oxygenation in chronic cerebrovascular occlusive disease. *Eur J Neurol.* 2018 Nov;25(11):1326-1332. doi: 10.1111/ene.13725. Epub 2018 Aug 3. PubMed PMID: 29924461; PubMed Central PMCID: PMC6221180.
- 7: Liu JY, Xiong L, Stinear CM, Leung H, Leung TW, Wong KSL. External counterpulsation enhances neuroplasticity to promote stroke recovery. *J Neurol Neurosurg Psychiatry.* 2018 May 29. pii: jnnp-2018-318185. doi: 10.1136/jnnp-2018-318185. [Epub ahead of print] PubMed PMID: 29844246.
- 8: Li B, Chen S, Qi X, Wang W, Mao B, Du J, Li X, Liu Y. The numerical study on specialized treatment strategies of enhanced external counterpulsation for

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Impact of Enhanced External Counterpulsation on Heart Failure Rehospitalization in Patients With Ischemic Cardiomyopathy



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Heart failure (HF) affects millions of Americans and causes financial burdens because of the need for rehospitalization. For this reason, health care systems and patients alike are seeking methods to decrease readmissions. We assessed the potential for reducing readmissions of patients with postacute care HF through an educational program combined with enhanced external counterpulsation (EECP). We examined 99 patients with HF who were referred to EECP centers and received heart failure education and EECP treatment within 90 days of hospital discharge from March 2013 to January 2015. We compared observed and predicted 90-day readmission rates and examined results of 6-minute walk tests, Duke Activity Status Index, New York Heart Association classification, and Canadian Cardiovascular Society classification before and after EECP. Patients were treated with EECP at a median augmentation pressure of 280 mm Hg (quartile 1 = 240, quartile 3 = 280), achieved as early as the first treatment. Augmentation ratios varied from 0.4 to 1.9, with a median of 1.0 (quartile 1 = 0.8, quartile 3 = 1.2). Only 6 patients (6.1%) had unplanned readmissions compared to the predicted 34%, $p < 0.0001$. The average increase in distance walked was 52 m (18.4%), and the median increase in Duke Activity Status Index was 9.95 points (100%), p values < 0.0001 . New York Heart Association and Canadian Cardiovascular Society classes improved in 61% and 60% of the patients, respectively. In conclusion, patients with HF who received education and EECP within 90 days of discharge had significantly lower readmission rates than predicted, and improved functional status, walk distance, and symptoms. © 2016 Elsevier Inc. All rights reserved. (Am J Cardiol 2016;117:901–905)

In March 1995, the US Food and Drug Administration granted 510(k) clearance to market enhanced external counterpulsation (EECP) for the treatment of angina pectoris, acute myocardial infarction, and cardiogenic shock. Clinical indications expanded in 2002 to include heart failure (HF). An EECP characteristic of particular relevance to the population with HF is the systolic unloading of the left ventricle during deflation, resulting in reduced afterload and improved ejection fraction. HF affects roughly 5.7

million Americans, causes over 1,000,000 hospitalizations each year, and was estimated to cost 32.4 billion dollars in 2015, with millions of dollars attributed to 30-day readmission penalties.^{1–3} Thus, health care systems and patients alike are seeking innovative methods to decrease readmissions. In 2007, Soran et al.⁴ observed an 83% post-treatment reduction of hospitalization for ischemic patients with low ejection fraction. In other studies, EECP improved quality of life, increased exercise tolerance and peak volume of oxygen consumption, and improved New York Heart Association (NYHA) classification.^{5–8} As attention centers on HF readmission as a target of clinical effectiveness, the role of tailored EECP programs coupled with education regarding medication and diet is worthy of examination and is the purpose of this report.⁹

Methods

Legacy (Trinity) Heart Care provided EECP treatment using Vasomedical Inc. equipment at standalone facilities in multiple US metropolitan areas to patients referred from hospitals and practitioners for EECP therapy. After receiving patients' informed consent and institutional review board's approval, the program tracked patients with HF due to ischemic cardiomyopathy who were referred for treatment after hospitalization from 65 physicians. These patients were

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See page 905 for disclosure information.

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