



February 10, 2020

TO BE SUBMITTED ELECTRONICALLY to MedicarePhysicianFeeSchedule@cms.hhs.gov

The Honorable Seema Verma
Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: Division of Practitioner Services, Potentially Misvalued Codes
Baltimore, MD 21244

RE: Supplemental Information for Misvalued Code G0166

Dear Administrator Verma,

Legacy Heart Care (Legacy) appreciates the opportunity to provide this supplemental information in response to the nomination of External Counterpulsation (ECP) therapy, HCPCS code G0166, as potentially misvalued. We strongly believe that ECP therapy, a non-invasive treatment for patients with debilitating angina, is significantly undervalued and that the current reimbursement does not reflect that actual inputs required to deliver care. Specifically, we reiterate our concerns submitted in response to the Calendar Year (CY) 2020 Medicare Physician Fee Schedule (PFS) proposed rule that the reductions are a product of the following major errors:

1. CMS' contractor, StrategyGen, did not appropriately value the ECP therapy equipment that is currently associated with G0166;
2. When originally assessing the cost of the equipment associated with ECP therapy, there were specific omissions that have artificially deflated the cost to provide these services¹; and
3. The relative value units (RVUs) for G0166 do not reflect the clinical guidelines and requirements for delivering ECP therapy².

We note with gratitude that the Centers for Medicare & Medicaid Services (CMS) reviewed the information and comments received in response to the 2020 PFS proposed rule and made

¹ The American College of Cardiology acknowledged this oversight in the attached letter to CMS (Attachment 1).

² The ECP User Manual is attached (Attachment 2).



swift corresponding updates based on invoice submissions to more accurately capture the cost of the ECP system (EQ012). We also thank the Agency for acknowledging that there are other essential equipment items critical to administering ECP therapy (finalized as proxy code EQ138) that have, since the inception of the code, been omitted from the direct practice expense (PE) inputs.³

This submission is intended to guide CMS in determining:

1. Accurate pricing for the additional package of required equipment items;
2. The appropriate time and associated minutes for delivering ECP therapy; and
3. Accounting for the service and maintenance costs not captured in the PE formula.

We thank CMS for recognizing that there are additional equipment items not reflected in the value of ECP therapy, which individually fall under the \$500 threshold for equipment pricing, but are nonetheless required and therefore should be counted as a direct PE input for ECP therapy. We recognize, as CMS notes, that the additional equipment items are not currently included in the direct PE inputs, but appreciate CMS acknowledging the necessity of such a package to ensure G0166 is appropriately valued. Further, we appreciate CMS' statement that EQ138 represents an instrument pack, not the "table [ECP] accessories", which indicates that EQ138 alone is not representative of the cost of the required ECP equipment items. As reflected in the attached 43 invoices and summary spreadsheet, EQ138 does not represent the costs associated with the total equipment package required for ECP therapy and significantly undervalues the cost of such equipment.

In addition, we appreciate that CMS finalized the proxy equipment package at the same equipment time used by the ECP system. We have included the results of an independently conducted time/motion research study on the delivery of ECP therapy. This data demonstrates there is additional time not reflected in the current 73 minutes that is required pursuant to the ECP User Manual. We request that the Agency update the minutes for both the ECP system and the ECP equipment package accordingly.

Background

³ 84 FR 62605.



Prior to the reimbursement reduction that went into effect January 1, 2019, reimbursement for ECP therapy remained stable for more than a decade. Despite its clear benefit in improving clinical outcomes and reducing preventable costs to the Medicare program, this service has been underutilized, primarily due to access issues and reimbursement not reflective of costs. The reimbursement reductions starting last year have compounded these concerns, as some ECP therapy providers no longer provide this service. We were forced to close our Kansas City clinic due to the reimbursement cuts and have since treated patients over multiple weeks at our Fort Worth, Texas clinic **who traveled from the Kansas City-area to obtain treatment due to a lack of access** in Kansas and neighboring states.

In 2018, the non-facility (NF) PE RVU for ECP therapy only captured the ECP system (\$150,000) and omitted the other essential equipment items. As a result of the market-based supply and equipment pricing transition and changes in labor and supply inputs, the reimbursement for 2019 was expected to decrease significantly. While this reduction was capped by the phase-in, the remaining reimbursement decrease was applied to ECP therapy beginning January 1, 2020 adding further pressure and challenges for us to sustain access for our patients. The table below illustrates the history of the market-based transition and proposed and final policies for 2020.

	2018	2019	2020 (proposed)	2021 (proposed)	2022 (proposed)
ECP System	\$150,000	\$127,873	\$124,413 (\$105,745)	\$120,954 (\$83,618)	\$117,495 (\$61,491)
Equipment Package	N/A	N/A	Proxy (EQ138)	TBD	TBD

We reiterate our appreciation that CMS took steps to correct the ECP system price error and added the proxy code for the additional equipment package. As noted in the table above, the adjustment to the ECP system price was significant and the inclusion of the proxy equipment package appropriately recognizes that there are other required items essential to delivering ECP therapy. As CMS acknowledged in the CY 2020 PFS final rule, following a review of invoices and additional information submitted in response to the proposed rule, the result of the market-based transition was inaccurate. The incorrect pricing of the market-based transition effectively created a false bottom for this code. The first year impact of the ECP system reduction was significant - more than \$22,000 - creating an extreme reduction in the reimbursement that may not have been felt otherwise. This error had real-life impacts - patients



could not access this therapy in the community and jobs were lost. As noted, we closed our Kansas City clinic, but we also reduced staff across all Legacy centers by 20%. If the system was correctly valued in 2019, the four-year transition to \$117,495 would have resulted in a reduction of \$8,126 per year.

Recognizing the significant direct PE input omissions, the American College of Cardiology (ACC) presented new recommendations to the RUC at the October 2019 RUC meeting. While we do not know what specific recommendations the RUC ultimately provided CMS, we are providing additional context and supplemental information in support of the ACC's submission.⁴ Our hope is that this information will assist CMS in determining the appropriate PE inputs and serve as a complement to the RUC's recommendations. **We believe this correction is critically important to ensuring ECP therapy is accurately reimbursed so that patients have access in their communities.**

ECP Equipment Package

In addition to the cost of a new ECP system (EQ012, \$117,495, Reasonable Useful Life (RUL) of 5 years), **there are additional equipment items that are essential to the functionality and delivery of ECP therapy that are not captured by EQ012.** These include cuffs, bladders, hoses, extenders, straps, cables, adapters, and other equipment items that typically cost \$18,744 per year (\$93,720, RUL of 5 years).⁵

While the ACC submitted separate packages (compression/electrical) for the RUC's consideration, we believe it would be simpler for the Agency to include all of these items into a single equipment package with a RUL of one year, which can be scaled up to 5 years to match that of the ECP system, if preferred. As noted in the table below, the additional equipment items have varying useful life spans. In general, the compression equipment items can be used for 100 treatment hours (or 3 months). This life span reflects the typical wear and tear with inflating the compression items at 300 mm Hg every heartbeat that we see in our practice and is consistent with the manufacturer's estimated usage.⁶ In our experience, the other patient

⁴ The ACC's RUC submission is attached (Attachments 5 and 6).

⁵ See Equipment Package (Attachments 3).

⁶ See Manufacturer's Estimated Usage (Attachment 8).



safety and monitoring equipment items typically have a useful life of 400 treatment hours (or 1 year), also consistent with the manufacturer’s estimated usage.

For the Agency’s consideration, we are submitting 43 invoices that reflect the price of the additional equipment items required to deliver ECP therapy.⁷ An overview table is below. This table captures the essential equipment items that are required to deliver ECP therapy and should be incorporated in a comprehensive equipment package.

Required Items	Useful Life	Item Description	Price/Unit	Price/One Year RUL
Compression Equipment Items	3 Months (100 hours)	Hose, Set (Models MC2, TS3, TS4 & Lumenair) (x6)	\$360.00	\$8,640.00
		Cuff, Thigh (x6)	\$170.00	\$4,080.00
		Cuff, Calf (x6)	\$75.00	\$1,800.00
		Bladder Set (x6)	\$65.00	\$1,560.00
		Treatment Pants (x12) (7 sets per year)	\$17.50	\$1,470.00
		Ankle Strap (x1)	\$30.00	\$120.00
		Abdominal Extension Strap (x2)	\$20.00	\$160.00
		Hose Adapter (x6)	\$2.25	\$54.00
		Hose Connector (x6)	\$4.50	\$108.00
Patient Safety/ Monitoring Equipment Items	1 year (400 hours)	Finger Plethysmograph (Models TS3 and TS4)	\$325.00	\$325.00
		3 Lead Integrated ECG Cable (Model TS3 includes adapter)	\$175.00	\$175.00
		Spo2 Probe (LumenairTM and Model TS4) Finger Clip	\$252.00	\$252.00
Total			\$18,744	

The attached spreadsheet includes a crosswalk of the equipment items, price per unit, units required per ECP system, sets required per year, and one year totals. A separate attachment includes the corresponding equipment item invoices.

⁷ See Equipment Package Invoices (Attachment 3).



Time Required to Provide ECP Therapy

An experienced clinical research professional not employed by Legacy conducted a time/motion study of the delivery of ECP therapy across 75 patients.⁸ The researcher assessed the time required for various components of the required activities as outlined in the ECP User Manual, which was developed by the primary manufacturer of ECP equipment and consistent with the guidelines established by the Joint Commission on Accreditation of Healthcare Organizations. Ultimately, the researcher concluded that the average time to provide ECP therapy was 100 minutes - an increase of 27 minutes over the current 73 minutes. The ACC accepted the results of this study and incorporated some of the findings into its RUC recommendation. An overview of the time required for the labor tasks compared to current NF minutes and the ACC recommendation is included below.

CA code	Activity description	Current NF minutes	Time/motion study	ACC RUC submission
CA009	Greet patient, provide gowning, ensure appropriate medical records are available	3	3	3
CA010	Obtain vital signs	3	6	6
CA013	Prepare room, equipment and supplies	2	2	2
CA016	Prepare, set-up and start IV, initial positioning and monitoring of patient	2	7	6*
CA008	Perform regulatory quality assurance	0	8	*
CA021	Perform procedure/service---NOT directly related to physician work time	60	64	68*
CA024	Clean room/equipment by clinical staff	3	4	3*
CA027	Complete post-procedure diagnostic forms, lab and x-ray requisitions	0	3	3
CA035	Review home care instructions, coordinate visits/prescriptions	0	3	2*
	Total	73	100	93*

* Indicates discrepancy between time/motion study and ACC's submission, explained below.

Legacy aligns with and supports the ACC's recommendation regarding CA010 and CA027. As ACC notes, the ECP User Manual requires obtaining vital signs (CA010) before and after each

⁸ See Time/Motion Study (Attachment 4).



session (3 minutes each). Further, the ECP User Manual requires clinical staff to perform post-procedure waveform calculations and analysis (CA027), which is an additional 3 minutes.

There are a few discrepancies between the time/motion study and the ACC recommendation, as discussed below. While the ACC accepted and relied on the results of the time/motion study when making its recommendation to the RUC, it was constrained by certain activity standards and guidelines. For example, CA016, CA024, and CA035 have activity standards and guidelines that only permit certain minute increments.

- CA016 was measured as 7 minutes in the time/motion study. ACC recommended 6 minutes, which it believes is reflective of the time to ensure patient positioning and the difficulty of wrapping the 6 pressure cuffs necessary to maximize therapeutic benefit.
- CA024 was measured as 4 minutes in the time/motion study, but is standardized to 3 minutes by RUC process (and therefore ACC submitted 3 minutes, instead of 4).
- CA035 was measured as 3 minutes in the time/motion study, but is standardized to 2 minutes by RUC process (and therefore ACC submitted 2 minutes instead of 3). We also note that this clinical activity is performed by registered nurses, with a rate per minute of 0.51 (L051A).

We agree with the rationale for the labor time for CA016, CA024, and CA035 as recommended by the ACC.

With respect to CA021, ACC recognized that the typical procedure/service time is longer than the 60 minutes associated with actual therapy delivery. As noted in the time/motion study, the typical therapy time is 64 minutes, due to the fact that a patient will have to void (due to increased blood flow and pressure to the bladder during therapy), meaning the patient must be disconnected and then reconnected to the equipment. However, we disagree with the ACC's total minutes, as it does not fully account for the additional activities ECP therapy providers must perform while the patient is on the equipment, but before therapy is delivered.

Specifically, ECP therapy clinical staff must perform certain patient quality activities including auscultation assessment of lung sounds, patient assessment of changes in angina frequency and severity, and checking for skin breaks on lower extremities (identified in the time/motion study as CA008, 8 minutes). The time/motion study identified the CA008 activities technically as "pre-service", because this occurs before therapy is delivered. We do not feel strongly about whether this time should be captured as pre- or intra-service, but submit for CMS'



consideration the time spent performing such activity (8 minutes). This time should be added to the typical procedure performance time (64 minutes), totaling 72 minutes for procedure/service time.

Based on the results of the time/motion study, the ECP User Manual policies and procedures, and the clinical activity standards and guidelines, we believe the appropriate NF minutes for ECP therapy should be 97. The table below delineates the minutes by activity.

CA code	Activity description	NF Minutes
CA009	Greet patient, provide gowning, ensure appropriate medical records are available	3
CA010	Obtain vital signs	6
CA013	Prepare room, equipment and supplies	2
CA016	Prepare, set-up and start IV, initial positioning and monitoring of patient	6
CA021	Perform procedure/service--NOT directly related to physician work time	72
CA024	Clean room/equipment by clinical staff	3
CA027	Complete post-procedure diagnostic forms, lab and x-ray requisitions	3
CA035	Review home care instructions, coordinate visits/prescriptions	2
	Total	97

ECP System (EQ012) Maintenance and Service Contracts

A critical part of delivering ECP therapy is ensuring that the ECP system (EQ012) be serviced and maintained regularly. This is due to the high-pressure intensity of the service required for clinical efficacy. Any interruption in service results in discontinued therapy, reducing ECP’s overall benefit, and may result in the need for the patient to restart the 35 visit protocol from the beginning. Such service contracts can be more than \$7,640 annually per therapy system.⁹ We recognize that there is an element in the PE formula to capture typical maintenance costs. However, due to the elevated rate of deterioration of internal parts from the consistent high-pressure environment, the typical ECP system cost and need for maintenance on these units do not conform to the regular PE formula. Adoption of these costs as a new input will address shortcomings in the valuation of EQ012.

⁹ See Service Contract Invoices (Attachment 7).



As noted above, the ACC submitted separate packages, including for the service contracts, for the RUC's consideration. Subsequently, we believe the cost of EQ012 should also reflect the annual service contracts (\$7,640 annually per therapy system, captured in Attachment 7), as the service repairs and maintenance for the ECP system are beyond what is typically captured in the PE formula. We believe these costs should be incorporated into the base equipment cost for EQ012 to reflect their necessity in maintaining effective functioning of the pneumatic compression and regular replacement/maintenance of the moving parts and pieces. Failure of a critical part of the equipment has historically been the most common reason for patients to lose access to care; past reimbursement has not allowed typical providers of ECP to invest in the service contracts, and when a critical component fails it presents a larger challenge to repair.

Thank you for your consideration of this information. I welcome the opportunity to speak with you to answer any questions you may have, clarify any concerns, and ensure Medicare beneficiaries continue to have access to this low-cost, high-quality, and decidedly value-creating service. Please feel free to contact me at 817.723.8893.

Sincerely,

A handwritten signature in black ink, appearing to read "M. Gratch", written in a cursive style.

Michael Gratch
President

ATTACHMENTS

1. ACC letter to CMS dated May 13, 2019.
2. ECP User Manual
3. Equipment Package and Invoices
4. Time/Motion Study
5. ACC RUC Submission - PE Summary of Recommendation for G0166
6. ACC RUC Submission - PE Spreadsheet for G0166



7. ECP Service Contract Invoices
8. Manufacturer's Estimated Equipment Usage