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QUALITY AND OUTCOMES

Cost-Effectiveness of Remote Cardiac Monitoring With the CardioMEMS Heart Failure System

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Heart failure (HF) is a leading cause of cardiovascular mortality in the United States and presents a substantial economic burden. A recently approved implantable wireless pulmonary artery pressure remote monitor, the CardioMEMS HF System, has been shown to be effective in reducing hospitalizations among New York Heart Association (NYHA) class III HF patients. The objective of this study was to estimate the cost-effectiveness of this remote monitoring technology compared to standard of care treatment for HF. A Markov cohort model relying on the CHAMPION (CardioMEMS Heart Sensor Allows Monitoring of Pressure to Improve Outcomes in NYHA Class III Heart Failure Patients) clinical trial for mortality and hospitalization data, published sources for cost data, and a mix of CHAMPION data and published sources for utility data, was developed. The model compares outcomes over 5 years for implanted vs standard of care patients, allowing patients to accrue costs and utilities while they remain alive. Sensitivity analyses explored uncertainty in input parameters. The CardioMEMS HF System was found to be cost-effective, with an incremental cost-effectiveness ratio of $44,832 per quality-adjusted life year (QALY). Sensitivity analysis found the model was sensitive to the device cost and to whether mortality benefits were sustained, although there were no scenarios in which the cost/QALY exceeded $100,000. Compared with standard of care, the CardioMEMS HF System was cost-effective when leveraging trial data to populate the model.

KEYWORDS

cost effectiveness, quality, heart failure, monitoring, economic analysis

1 | INTRODUCTION

Heart failure (HF) currently affects 5.7 million adults in the United States, with the prevalence projected to increase.[1,2] There is a decrement in health-related quality of life, likely related to disease progression and frequency of hospitalization,[3] as well as psychological and financial burdens on caregivers of HF patients.[4] The economic burden of HF is also substantial and estimated at more than $30 billion annually in 2012.[3] As an important cost driver is hospital readmissions for patients following decompensation,[5] technologies and advances that minimize likelihood for readmission could minimize costs and the associated patient and caregiver burden.

Remote monitoring technologies have come under consideration for their ability to slow progression of symptomatic HF.[6] Review articles' findings have been mixed; in general, there is support for the concept of remote monitoring with differences in reported effectiveness of specific programs and technologies.[7–9] Telemonitoring was not shown to reduce readmission rates significantly in 2 recent large studies.[10,11] Remote monitoring may be more beneficial for certain populations than others,[12] although few studies have examined this question in detail. However, recent published studies have started to explore the literature on remote monitoring to understand variation in success rates and the inconsistent definition of *remote* monitoring.[7,13,14] The effectiveness of remote monitoring may also depend on the particular monitoring device/system or patient characteristics.[15,16]

Positive results have been demonstrated in a clinical trial involving a recently Food and Drug Administration (FDA)–approved implantable wireless pulmonary artery pressure monitoring system (CardioMEMS). The CardioMEMS Heart Sensor Allows Monitoring of Pressure to Improve Outcomes in NYHA [New York Heart Association] Class III Heart Failure Patients (CHAMPION) trial[17,18] utilized a

single-blind, randomized design to compare patients who received the CardioMEMS device and pulmonary artery (PA) pressure-guided management for a minimum of 6 but an average of 18 months, with control patients who received the device but did not transmit data, essentially receiving usual care. An open access extension in which control patients also received pressure-guided management followed; average open access extension follow-up was an additional 13 months. These studies identified a sustained and significant decrease in hospitalization for class III NYHA patients compared with controls, as well as benefits in patient-reported utilities, as measured during the first year. Further analyses also support these findings using trial data[18,19] and at a high-volume stand-alone cardiology center.[20] Given the high cost of HF hospitalizations, the availability of an intervention that has been shown to significantly reduce hospitalizations is a potential paradigm shift in HF treatment. However, as with any implanted device, the initial investment costs must be carefully weighed against potential longer-term savings compared to usual care.

The purpose of this study was to develop a Markov simulation model to estimate the cost-effectiveness of the CardioMEMS HF System at up to 5 years compared to usual care in the indicated population.

2 | METHODS

A Markov model was developed to estimate cost-effectiveness of the CardioMEMS HF System compared with usual care over a 5-year period. The model has 3 primary types of inputs, namely clinical events, costs, and utilities. The output is the incremental cost-effectiveness ratio (ICER), that is, the difference in costs divided by the difference in utilities, of CardioMEMS vs usual care. Patients accrue clinical events (hospitalizations, complications), costs (routine care, monitoring, hospitalizations), and utilities in each 1-month cycle until they die or complete 60 cycles. Figure 1 illustrates the structure. Patients with HF enter the model. The model structure is identical for patients who receive the CardioMEMS device and usual care, but event rates differ. In either cohort, patients may remain stable and not incur hospitalizations, or they may require a hospital admission. After each cycle, patients who are still alive cycle back and can enter the following cycle either as a stable outpatient or requiring hospitalization. When patients die, then they no longer accrue costs or benefits (utilities). Patients who have a hospitalization also have a different rate of accrual of utilities in the immediate posthospitalization cycle. This posthospitalization state is not represented as a separate health state in this visual representation of the model.

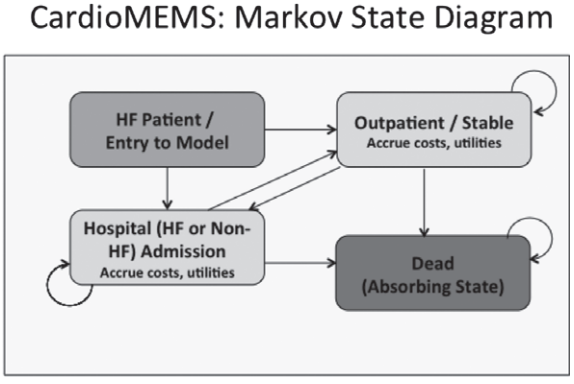

FIGURE 1 Model structure. Abbreviations: HF, heart failure.

2.1 | Clinical data sources

As much as possible, published CHAMPION trial findings were used to populate the model. Clinical inputs for the base case, including the rate of implant-associated complications, mortality, and the rate of HF-related and non–HF-related hospitalizations appear in Table 1. Details of the approach appear in the Supporting Information, Appendix, in the online version of this article.

2.2 | Utility data sources

The CHAMPION trial collected utilities from patients at baseline, 6 months, and 12 months using the EuroQol (EQ)-5D-3L.[21] Health utilities are a measure of well-being that range from 0 to 1, with 0 indicating immediate death and 1 indicating perfect health. There are a number of methods to elicit utility values from respondents; the EuroQol EQ-5D-3L is a widely used tool. Utilities are represented as a single value to adjust for the patient's life-years. For example, someone who spends 5 years in a health state that he or she rates as 0.80 would accrue 4.0 quality-adjusted life-years (QALYs) during that 5-year period.[22]

Across both groups, the baseline utility score was 0.711. There are 2 ways in which utilities are used in the model. First, there is a change over time, from enrollment and randomization to the end of the trial's utility observation period. As values were not collected after 12 months, assumptions were made about how to assign utilities after the end of the observed period to reflect the natural history of HF. These assumptions are detailed in the Supporting Information, Appendix, in the online version of this article. Although changes in utilities over time are likely not linear, for the sake of the model, it is assumed that changes from baseline to 6 months and from 7 to 12 months are linear, with the exception of decreases associated with hospitalizations. Furthermore, the model's base case assumes that there is no change in utility values over time; that is, the value at 12 months is carried forward to the remainder of the cycles for each patient unless they are hospitalized or die. The alternatives, explored in sensitivity analyses, include having the values increase or decrease incrementally over time, reflecting how utility values may increase with the duration of time since the most recent hospitalization or may decrease over time as the patient ages.[23] These 3 options—increase, decrease, or remain the same—cover all possibilities.

Second, the model incorporates a decrement in utilities to reflect what is known about the burden of hospitalization in HF. The impact of hospitalization on utilities was not directly assessed in the CHAMPION trial; thus, other published sources were reviewed for guidance. Details of the approach appear in the Supporting Information, Appendix, in the online version of this article.

TABLE 1 Base case input parameters: clinical events and utilities

Parameter	CardioMEMS	Standard of Care	Source(s)
Implant complications	1.4%	0%	CHAMPION
Mortality			
Randomized period	18.5%	22.9%	CHAMPION
Open access period	14.7% (pooling groups across open access period)	22.9% (carrying forward randomized period rate)	CHAMPION
Hospitalization			
Randomized period	1.38 events per patient-year	1.65 events per patient-year	CHAMPION
Open access period	1.31 events per patient-year	1.65 events per patient-year (carrying forward randomized period rate)	CHAMPION
Hospitalization, % HF			
Randomized period	33%	42%	CHAMPION
Open access period	36%	42% (carrying forward randomized period distribution)	CHAMPION
Remote monitoring			
All months	100%	20%	Gharacholou et al[41] (percent referred for disease management)
Patient distribution, % Medicare	75%	75%	Assumption
Utilities			
Baseline	0.711	0.711	CHAMPION
Change, months 1–6	0.001	−0.005	CHAMPION (distributed evenly over interval)
Change, months 7–60	0.003	−0.003	CHAMPION (distributed evenly over interval)
Cycle of hospitalization, decrement	0.045	0.045	Assumption, based on Gohler et al[23]
Cycle following hospitalization	0.0225	0.0225	Assumption, based on Gohler et al[23]
Change over time	LOCF	LOCF	Assumption

Abbreviations: CHAMPION, CardioMEMS Heart Sensor Allows Monitoring of Pressure to Improve Outcomes in NYHA Class III Heart Failure Patients clinical trial; HF, heart failure; LOCF, last observation carried forward.

2.3 | Cost data sources

Several types of costs were required for the model: implant cost, implant procedure cost, complications cost, routine monitoring, CardioMEMS-related monitoring, HF and non-HF hospitalizations. Table 2 presents costs used in the model and their corresponding sources. The base case of this model used estimates from a recent analysis of the Truven Health MarketScan April 2008 to March 2013 Commercial Claims and Encounters and Medicare Supplemental and Coordination of Benefits Database[24] for complication costs, as no other published data were available. This MarketScan data analysis, as well as other published studies,[25,26] were used for costs of HF and non-HF hospitalizations. Costs were inflated to 2016 US dollars.

TABLE 2 Base case input parameters: costs

Parameter	Cost (USD)[1]	Source(s)
CardioMEMs device (per device)	$17,750	Average sales price
Implantation procedure	$1,280	Medicare: $1,138; CPT 93451, 93568, 33210, 2016 MFS; Commercial: $1,707 (MFS × 1.5)
Complications, each	$5,770	Martinson et al[24] inflated to 2016
Hospitalizations		Takes into account % Medicare vs commercial
HF hospitalization	$21,007	Martinson et al[24] inflated to 2016
Non-HF hospitalization	$24,367	Martinson et al[24] inflated to 2016
Monthly monitoring	$47	Martinson et al[24] inflated to 2016
Outpatient costs, routine care (per year)	$19,576	Martinson et al[24] inflated to 2016

Abbreviations: CPT, Current Procedural Terminology; HF, heart failure; MFS, Medicare Fee Schedule.

[1] Costs are presented in 2016 dollars and were inflated or discounted as described in the Methods. All costs are weighted based on the assumption that 75% of patients are covered by Medicare and 25% have commercial coverage.

2.4 | Other assumptions

The model assumed that 75% of the population is covered by Medicare and 25% are covered by commercial insurers. A 3% annual discount rate for costs and outcomes (ie, utilities) was used.

2.5 | Sensitivity analyses

Sensitivity analyses systematically explored variations in costs and clinical differences between treatment and standard of care (SoC) groups in mortality and hospitalization rates.

The model was developed and implemented in Microsoft Excel (Microsoft Corp., Redmond, WA).

3 | RESULTS

Based on the model's base case, half (50.4%) the original CardioMEMS patients were dead at 60 months; in the SoC group, mortality exceeded 50% earlier (at 40 months). At the end of the 60-month model time horizon, 49.6% of CardioMEMS patients and 23.8% of SoC patients remained alive.

The cost of device and implantation, including treatment of complications, totaled $19,111. The cost over the 5-year observation period was approximately $162,772 per patient among SoC patients and $188,880 (including the device and implantation) in CardioMEMS patients. The difference in QALYs was 0.58, favoring the CardioMEMS patients (2.51 compared to 1.93 among SoC patients). Table 3 shows total costs and total utilities accrued by the 2 groups over the 5-year observation period. The base case of the model estimated the incremental cost-effectiveness ratio of CardioMEMS compared to SoC as $44,832 per QALY.

Sensitivity analyses appear in Figure 2 and the Supporting Information, Table, in the online version of this article. Inputs that highly influenced the cost/QALY included device cost and cost of routine outpatient care. Device cost, even when it was increased to $20,759, still resulted in a cost/QALY < $50,000, remaining in the high-value space, using the guidelines sponsored by the American College of Cardiology and American Heart Association.[27] Even doubling the device price resulted in a cost/QALY of < $76,000, well within the intermediate-value space. Alternative costs for outpatient care included an estimate less than half of the base case used in the model ($6,930[28]); using this estimate as a model input resulted in a cost/QALY of $33,040, reflecting that the longer-living treatment patients had lower outpatient expenses over the modeled period. The multiple ways in which this model varied utilities to reflect the natural history of disease had little influence on outcomes. A different baseline utility value for patients, such as the 0.55 that another team derived based on an algorithm to convert the Minnesota Living with Heart Failure Questionnaire,[29] also had a small influence on the cost/QALY. It should be noted that some of the sensitivity analysis results are symmetrical around the base case; others are appropriately not symmetrical.

Multivariate and threshold analyses explored additional scenarios to include alternative inputs or to identify input values that would make the cost/QALY meet or exceed various thresholds (Supporting Information, Table, in the online version of this article and Figure 2).

TABLE 3 Model results: base case

	CardioMEMS	Standard of Care
Five-year costs and outcomes		
Total costs	$188,880	$162,772
Implant: device, procedure, complications	$19,111	$0
Inpatient costs	$108,124	$113,199
Outpatient costs (including monitoring)	$61,645	$49,573
Total accumulated QALYs	2.509	1.926
Incremental cost-effectiveness ratio (cost per QALY gained)	$44,832	

Abbreviations: QALY, quality-adjusted life year.

4 | DISCUSSION

With the substantial societal and economic impact of HF, technologies that can help minimize the likelihood for readmission and cost of care associated with HF may provide significant benefits to the healthcare system. With positive clinical evidence behind the CardioMEMS HF System remote pulmonary artery pressure monitoring device, this study sought to evaluate the cost-effectiveness of the device. This analysis demonstrated that the estimated cost/QALY of CardioMEMS compared to the standard of care (non–PA-guided medical management) was $44,832, within the range of what is considered highly cost-effective. This finding puts CardioMEMS in the high-to-intermediate value according to the American College of Cardiology/American Heart Association[27] and other organizations.[30,31] Findings were consistent across a range of sensitivity analyses.

With constrained resources for healthcare expenditures, it is reasonable to expect evaluation of new technology not just on safety and efficacy but also cost-effectiveness and value. Findings on cost-effectiveness of treatments to manage HF range widely, in terms of the incremental cost-effectiveness ratios that they present as well as the interventions and patient groups compared. Clinical guidelines are moving toward considering level of value as part of the evaluation, with interventions with an ICER of less than $50,000/QALY being classified as having high value, $50,000 to < $150,000/QALY having intermediate value, and those with a higher cost/QALY of low value.[27] Use of guideline-directed therapy vs diuretics alone was found to be highly cost-effective (<$1,500/QALY) and often cost saving.[32] Among reduced ejection fraction HF patients, ICERs associated with treatment with eplerenone were < £10,000 in the UK and < €10,000/QALY in Spain.[33] Among patients with advanced HF, the ICER of left ventricular assist devices has been shown to range from $127,887 to $209,400/QALY compared to optimal medical management.[34–36] Adding resynchronization therapy to implantable cardioverter-defibrillators among mild HF patients was found to be of intermediate value, with an ICER of $61,700.[37] The findings from this model placed the CardioMEMS HF System in the high-value or intermediate-value categories.

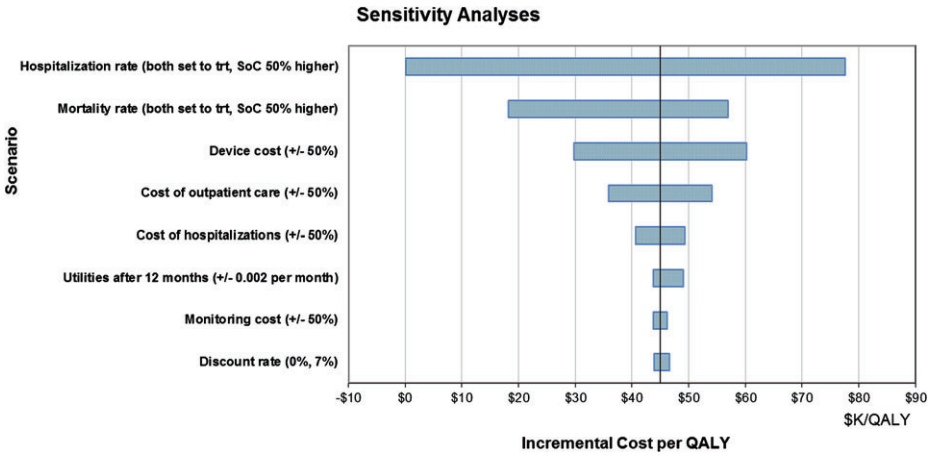

FIGURE 2 Tornado diagram. The vertical line the near center of the figure represents the base case result ($44,832/QALY). Abbreviations: QALY, quality-adjusted life years; SoC, standard of care; trt, treatment.

The findings from this model are robust and consistent with guidelines on model development and testing that recommend use of real world evidence as much as possible.[30,38–40] Our findings generated cost/QALY estimates that differed from 2 recent publications describing models comparing CardioMEMS HF System to usual care,[24,29] with the present analysis finding a cost/QALY falling between the other publications. Some of these differences are due to the different hospital and outpatient cost inputs utilized. There is no consensus on hospitalization costs for HF patients, so some differences across models may be expected. Our analysis used hospital costs that were similar to those used by Martinson et al,[24] as we found these to be the most recent and relevant cost estimates available in the literature. We adjusted the values utilized from 2014 to 2016 to account for inflation, which accounts for an increase in costs of 5%. Another assumption that varied across models is the proportion of standard of care patients who received some sort of monitoring with its associated monthly cost. The Martinson et al[24] study assigned a cost to 25% of patients based on expert opinion; we assumed only 20% in the base case,[41] whereas it is unclear if the Sandhu et al[29] study assigned a similar cost to SoC patients. Given the low monitoring cost assigned, the impact is relatively limited; in a sensitivity analysis, the cost/QALY only increased to $45,320 when we assigned no monitoring costs in the SoC patient cohort.

Other differences in model structure and inputs were more notable. The Sandhu et al article did not use mortality findings from the CHAMPION trial.[29] The authors in that study suggested that the analysis was not powered for mortality; however, recent recognition of the challenges in powering studies for all relevant economic endpoints suggests that it is preferable to use underpowered real-world findings than to make assumptions.[42] Similarly, the model by Sandhu and colleagues did not use trial data on patient utilities, but instead elected to convert scores from the condition-specific quality-of-life measure included in the trial.[29] The different source for utilities and the difference in how hospital-related decrements were assigned explained the variation in total accrued utilities between these 2 models. Our model also attempted to follow the natural history of the disease more closely and used longer and larger decrements in health utilities for each hospitalization. Finally, sensitivity analyses varied between these 2 models, because the present study tested values as proportion of the CHAMPION trial outcomes, whereas the prior study used alternative inputs from studies with patients who are not indicated for this intervention (ie, use of a population with a large proportion of patients with NYHA class II HF[29]). We encourage future development of the model as other indications are approved, but selectively choosing inputs from nonindicated populations seems speculative and introduces more uncertainty than it resolves. Another recent cost-effectiveness model of CardioMEMS also found it to be highly cost-effective.[21] A health economic simulation of the CardioMEMS system in Germany based on the CHAMPION trial data also found substantial benefits.[43]

The challenges of treating HF should not be understated. Approximately 5.7 million adults 20 years and older in the United States were estimated to have HF in 2012, with that number expected to exceed 8 million by 2030.[2] Most large-scale randomized trials using noninvasive monitoring approaches, in contrast to CHAMPION, have not demonstrated reduction in hospitalizations. The cost-effectiveness estimates generated from this model have leveraged trial data, considered the natural history of disease in the decrements and change over time in utilities, and the model was also designed to allow users to enter personalized inputs to reflect individual payers' situations. The incremental cost-effectiveness ratio with the CardioMEMS system is well within the range of existing interpretation guidelines,[27,30,31] as are plausible scenarios tested by sensitivity analysis, suggesting that the CardioMEMS HF System is worthy of consideration by payers in determining coverage for an otherwise costly chronic disease.

There are several limitations in this model and analysis that deserve consideration. First, the CHAMPION trial included a minimum 6-month, single-blind period (with an average of 18 months) and an additional mean 13-month open access period, requiring assumptions about the sustainability of benefits over the long term. The model took into account the possibility that the benefits would not continue to accrue after a period of time, but there remains uncertainty about inputs in the second half of the modeled period. These were considered in the sensitivity analyses. This model used findings from the open access period of the trial. One could argue that the changes in population characteristics between the randomized and open access dropout affects our ability to use these data. Given that the SoC cohort was receiving more intense, although not PA-pressure-guided, care than a typical population by nature of their study participation, it is likely that the trial design inherently minimized the effect of the intervention. For this reason, we determined that using open access period data was reasonable, because sensitivity analyses also explored carrying forward data from the randomized period. Second, there are additional analyses or data collection that

could have refined the model but are currently limited by the lack of data. For example, there has not yet been any analysis exploring the relationship between patient-reported utilities and number of hospitalizations, or if there are differences in utilities among patients who had none, 1, or multiple hospitalizations during an interval. These might allow the model to have different sets of scenarios for generally well vs sick patients in whom outcomes might vary. These different scenarios could, in turn, be useful to examine the effects of populations that differ from the CHAMPION population. Unfortunately, there were no data available on how utilities for patients in the CHAMPION trial were related to hospitalizations. We assumed a linear trajectory for increases or decreases in utilities and applied a short-term decrement associated with hospitalizations. It is possible that this could double-count decrements in utilities. However, sensitivity analyses that explored utilities overall and associated with hospitalizations suggest the influence of hospitalization-related utilities in the model was inconsequential as decrements were short term and small. Third, this analysis was operationalized as a deterministic model. Although there are certainly situations that require a stochastic approach, given the little that is known about the distributions for many of the input variables, using such an approach would not increase model accuracy. Multivariable sensitivity analysis can address similar concerns, though we believe that individual model users in decision-making capacities could best determine their own base case and extreme input values.

Another important limitation to this model and many other models estimating the cost-effectiveness of HF is that the direct medical costs are just 1 component of the total societal cost of care. There is an opportunity cost to repeated, possibly avoidable hospitalizations, in that other patients may be denied treatment based on limited availability. The time associated with remote monitoring using less technologically advanced systems might create a greater time burden on clinical staff. There are not yet time and motion studies comparing staff time on monitoring and responding to data from the CardioMEMS HF System compared to other technologies, but it seems plausible that the time required would be less than gathering a full report from the patient during a telephone call. Infrastructure improvements may be required to implement monitoring programs. Well-planned and implemented improvements could enhance the cost-effectiveness of the monitoring; a less organized or structured arrangement might limit the benefits of remote monitoring programs. A recent study of the CardioMEMS device monitoring at a single site collected data on the time required for nurses and physicians to review patient data[20]; these data can be used to develop an analysis of time savings on the part of healthcare providers that might be associated with remote monitoring. Beside the opportunity presented for managing patients with less time, there are other potential benefits. Fewer in-person outpatient visits could save transportation costs as well as caregiver time and costs, for the patients who are regularly assisted by a caregiver. The use of informal caregiving is common among HF patients[44] and can range from occasional help to moving closer to a parent[45]; and the burden on caregivers can be substantial.[46] There may be costs to insurers based on caregiver health, which can be impaired due to caregiving responsibilities. As these data become available, they should be incorporated to refine or modify these findings. Our findings are also specific to the CardioMEMS HF System and should not be taken to be reflective of all remote monitoring systems due to potential differences in clinical effectiveness, utilities, and cost. This model presented findings based on nationally representative costs and a population matching the CHAMPION characteristics. For this model to be more meaningful to decision makers, it should use local clinical and cost data as inputs.

5 | CONCLUSION

Among eligible patients with HF when compared with SoC, the CardioMEMS HF System was found to be cost-effective. These values were generally consistent across a range of sensitivity analyses. For HF patients meeting current indications, the CardioMEMS HF System may represent an important clinical advance, while at the same time being a cost-effective treatment for HF.

5.1 | Acknowledgments

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5.2 | Conflicts of Interest

Authors Jordana K. Schmier and Kevin L. Ong are employed by Exponent. Exponent received a grant from St. Jude Medical to evaluate the cost-effectiveness of its implantable remote monitoring system. Dr. Fonarow has served as a consultant to St. Jude Medical. St. Jude Medical has reviewed the manuscript prior to submission, but did not provide substantial scientific input.

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