Budget Impact Analysis to Estimate the Cost Dynamics of Treating Refractory Gastroesophageal Reflux Disease With Radiofrequency Energy: a Payer Perspective

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ABSTRACT

Purpose: A minimally invasive endoscopic treatment that utilizes radiofrequency energy (RFE) has received increased attention as an appropriate middle-ground approach in the treatment of refractory gastroesophageal reflux disease (GERD) and as an alternative to complicated and invasive surgical procedures. The objective of this study was to develop a longitudinal budget impact analysis from the payer perspective to estimate the direct medical costs of treatment for the refractory GERD patient population and to estimate the budgetary impact of further extending the RFE treatment option to other target populations.

Design and methodology: A retrospective analysis of claims designed to assess the longitudinal costs and budget impact on payer expenditures associated with managing and treating GERD surgically (Nissen fundoplication [NF]), endoscopically (RFE), or medically was performed. Both Medicare and commercially insured claims databases were interrogated for such population-level analyses.

Results: At current adoption rates (less than 1% of procedures), RFE demonstrated overall cost savings ranging from 7.3% to 50.5% in the 12-month time period following the index procedure (inclusive of procedure costs) when compared to medical management and fundoplication across the commercial and Medicare patient populations. Increasing the total number of RFE procedures to 2% of total cases performed generated per-member, per-month (PMPM) savings of $0.28 in the Medicare population and $0.37 in the commercially insured population. Further increases yielded higher PMPM savings.

Conclusion: Adding to the clinical importance of RFE in filling the gap between medical and surgical management, this economic analysis demonstrates to payers that the adoption of RFE can create notable savings to their plans when compared to surgery or medical management.

Key terms: GERD, radiofrequency energy, Nissen, fundoplication, Stretta, proton pump inhibitor, PPI

INTRODUCTION

Gastroesophageal reflux disease (GERD) is an extremely prevalent condition, with some studies suggesting that it affects between 18% and 27% of individuals in the United States (El-Serag 2014). Moreover, GERD imposes a significant disease burden worldwide and is rising in prominence globally. According to a report by the American Gastroenterology Association, GERD is the most costly gastrointestinal (GI) disease in the United States and was associated with about $142 billion in direct and indirect costs in 2009 (Peery 2012).

The most common first-line treatment for GERD is the use of proton pump inhibitors (PPIs), which have been demonstrated in clinical trials to be highly effective for both healing and symptom control. However, evidence is emerging that long-term use of PPIs may be associated with infectious complications, cardiac sequelae, and nutritional deficits (Shah 2015). Furthermore, PPI therapy is costly and contributes significantly to the overall cost burden of GERD, especially considering treatment of potential adverse effects. A review of Medicare Part D claims data revealed that a single agent used for PPI therapy cost the program about $2.5 billion in 2013 (Herman 2015).

GERD is considered refractory when patients do not respond to daily PPI treatment or when their response is incomplete. For people with refractory GERD, a minimally invasive endoscopic treatment that utilizes radiofrequency energy (RFE), branded as the Stretta System (Mederi, Norwalk, Conn.), has received increased attention as a middle-ground therapy before patients are subjected to complicated and invasive surgical procedures, specifically Nissen fundoplication (NF). After its approval by the FDA in 2000, Stretta demonstrated significant improvements in heartburn control, patient satisfaction, and patient quality of life (Aziz 2010, Arts 2012, Corley 2003, Dughera 2011, Perry 2012).

In 2012, the Society of American Gastrointestinal and Endoscopic Surgeons (SAGES) reviewed the findings of the available literature and recommended the use of RFE in refractory

GERD patients (Auyang 2013). Subsequent to the SAGES recommendation, research on the clinical efficacy of RFE has yielded mixed results. Some studies supported and reinforced the finding of previous studies that RFE mitigates GERD-related symptoms and improves patient quality of life (Dughera 2014, Lo 2015, Yan 2015), while others were unsuccessful in establishing sustained gains in objective clinical outcomes for RFE when compared to traditional surgical interventions (Hopkins 2015, Lipka 2015). As indicated in the SAGES guidelines, it is important to emphasize that the RFE procedure is not considered an alternative to effective PPI therapy.

Treatment-related costs associated with PPI therapy are difficult to quantify; however, a review of Medicare Part D claims data from 2013 shows that a single agent, esomeprazole, generated about $2.5 billion in costs alone (Herman 2015). In the general population, GERD may add as much as $3,355 per patient, inclusive of direct medical or therapy costs (81%) as well as indirect costs associated with lost productivity (19%) (Brook 2007). Not surprisingly, treatment of patients with refractory GERD is more expensive than treatment of patients with GERD that is treatable with PPIs. For example, the evaluation of patients with extra-esophageal reflux may cost as much as an additional $5,438 per patient, while the medical components could add as much as $5,154; during the first year of evaluation and treatment, costs among these patients are about 5.6 higher than the typical GERD patient ($51 billion versus $9 billion) (Francis 2013).

Empiric therapy with a PPI is often attempted as an initial strategy for patients assumed to have GERD. While this is effective in most cases, approximately 20% of patients will not fully respond to PPI therapy (Amos 2012) and continue to suffer from a high symptom burden, impaired quality of life, and reduced productivity—all of which can contribute to extraneous costs. For example, a review conducted at 53 primary and secondary care centers in the United States identified that incomplete response to PPI therapy (and in most cases, maximal PPI therapy) added $4,068 in direct costs per patient and $5,876 in indirect costs per patient (Stålhammar 2012).

GERD symptoms often mimic potentially life-threatening diseases, such as cardiac ischemia. One cost of GERD that is often overlooked is the evaluation of chest pain that might be a symptom of cardiac ischemia but turns out to be a symptom of GERD. Borzechi (2000) reviewed the cost implications of evaluation of noncardiac chest pain. This analysis identified about 180,000 cases a year costing about $750 million. About 60% of the cases were due to esophageal causes, with GERD being the most prominent diagnosis.

Evidence suggests that the use of RFE improves patient quality of life and may spare some patients from the side effects of prolonged PPI exposure as well as from the potential risks associated with invasive surgical interventions. Less clear are the cost implications of increased access to RFE in the treatment of refractory GERD. In order to address this question of cost, our present study enhances the existing clinical and economic profile of GERD with a specific focus on refractory GERD and its impact on all components of payer costs across a longitudinal period (12 months before and after the index procedure). We expect that this population-based research will assist policymakers, payers, and providers in evaluating the current treatment options available for refractory GERD that is both difficult and expensive to treat.

METHODS

Study design

This is a retrospective analysis of pre- and postprocedure medical claims designed to provide a longitudinal assessment of costs and budget impact to payers. Costs are defined as the total payments (also known as reimbursements) made to providers (allowed amounts), for managing and treating GERD with the four therapeutic options previously identified with respect to the following procedural index events as listed in the Current Procedural Terminology (CPT) and International Classification of Diseases Version 9 (ICD-9) coding manuals:

- Medical management (abbreviated in text and tables as MEDMGT) (index event: esophageal manometry, CPT code 91010); the CPT code for manometry was used to identify patients in the claims databases who were considered candidates for surgical intervention to treat their refractory GERD
- Outpatient fundoplication (NF-OP) (index event: fundoplication, CPT code 43280)
- Inpatient fundoplication (NF-IP) (index event: fundoplication, ICD-9 procedure code 44.66/44.67)
- Outpatient RFE (index event: RFE, CPT code 43257)

The above treatment options required a diagnosis code of 530.81, 530.11, 530.19 or 530.9x, (ICD-9 coding designations for diseases of the esophagus, stomach, and duodenum) along with the above noted CPT or ICD-9 procedure code to be assigned to the appropriate treatment group.

If an individual underwent multiple procedures spanning treatment categories, they were assigned to a primary treatment group in the following order: outpatient RFE, NF-IP, NF-OP, MEDMGT. Analyses were performed on the entire population of beneficiaries for whom payments were made to providers by Medicare and also by a major commercial health plan. De-

tails of the study population and data sources are discussed below.

Reimbursed costs for each treatment group were calculated for three distinct intervals of time: 12 months prior to their specific treatment procedure (preprocedure), the index event itself, and 12 months after their treatment procedure (postprocedure). In addition to costs associated with the index event, claims data for five components of care were retrospectively tracked over the course of the 24-month time period: inpatient care, hospital-based outpatient care, emergency room care, physician services, and pharmacy services. Inpatient care costs were limited to DRGs related to gastrointestinal disorders for both the Medicare and commercially insured populations.

Hospital-based outpatient care costs were identified using service code 22 (On Campus–Outpatient Hospital) as defined by CMS. Emergency room care costs were identified using CPT codes 99281–99285. Physician services and pharmacy (prescription) services costs were obtained from the OptumInsight Inc. (Eden Prairie, Minn.) commercial health plan data set and applied to both the commercially insured and Medicare analyses, as claim costs for these services are not available in the Medicare data sets. To accommodate differences in reimbursement levels between Medicare and commercial plans, the commercial costs for physician services were discounted by 20% when applied to the Medicare analysis. Where available, pretreatment and posttreatment utilization of services were tracked on a per-member basis for Medicare and commercially insured patients.

Reimbursements during the three time intervals and for the five service components were aggregated to obtain an overall mean cost for each treatment group. Treatment-specific total costs were then converted to per-member, per-month (PMPM) expenditures. It is important to note that all cases meeting the basic index diagnosis and procedure code criteria were included in the study, regardless of their cost or subsequent diagnostic profile, generating a real-world, population-based analysis that did not receive any outlier or other statistical adjustments.

Cost data

For the Medicare population, the index RFE procedure and its comparators as well as related post-procedure inpatient, outpatient, and emergency room were derived from the Medicare Inpatient Standard Analytical File (IPSAF) and the Medicare Outpatient Standard Analytical File (OPSAF) from calendar years 2011–2013, with 2012 representing the index year. The RFE procedure cost of $3,200 reflects a general market average for both Medicare and commercial payer populations. It represents a significant markup to the Medicare allowable cost for RFE and is approximately 90% of the national average from the OptumInsight database. Finally, cost data for physician and pharmacy services were imputed from the OptumInsight database.

For the commercially insured population, cost data for the index procedure and all of the five components of care were obtained from the OptumInsight database, which comprises claims generated by a national commercial health plan consisting of approximately 24 million members. Index cases were derived from those occurring in calendar years 2012 and 2013 to track pre- and postintervention payments.

Sensitivity analysis

To account for variability in adoption rates and expenditure levels, a sensitivity analysis was conducted to examine the estimated economic impact on PMPM expenditures of increased utilization of RFE (and corresponding decrease in other treatment options) associated with the index procedure and postprocedure costs. Costs from the preprocedure period were not included so as to isolate the effect of RFE adoption on subsequent accumulation of health plan expenses. The refractory GERD prevalence rate for this analysis was calculated to be 2.4% and was derived by assuming a 20% overall GERD prevalence rate and a 12% rate of refractory GERD within this population (Amos 2012). The adoption rate in this sensitivity analysis was permitted to vary from 1% to 5% of cases migrating to RFE.

RESULTS

Treatment-specific cases and demographics

Medicare Population

Applying the coding scheme described previously, the following case counts were derived from the 2011–2013 Medicare Inpatient and Outpatient Standard Analytic Files: RFE=23 cases; NF-OP=1,198 cases; NF-IP=2,226 cases, and MEDMGT=4,825 cases. The total population of cases entered into the Medicare cost analyses was 8,272, with no further outlier or diagnostic adjustments performed in order to preserve a broad population-level analysis. The prevalence of Medicare cases by procedure was as follows: RFE=0.28%; NF-OP=14.48%; NF-IP=26.91%, and MEDMGT=58.33%.

Table 1a presents the patient demographics of each treatment group under review in this study. In general, there were no material differences in gender across the treatment options, as all were heavily weighted toward females (RFE=65%, NF-OP=71%, NF-IP=71%, and MEDMGT=70%). With regard to age, NF-OP, NF-IP, and MEDMGT had similar age distributions throughout all age bands. RFE-treated patients were considerably fewer in the under-65 age band

compared to the other treatment options (RFE=13%, NF-OP=34%, NF-IP=33%, and MEDMGT=29%).

Commercially Insured Population

Applying the coding scheme described previously, the following case counts were derived from the commercially insured data set: RFE=64 cases; NF-OP=974 cases; NF-IP=1,825 cases; and MEDMGT=4,033 cases. The total population of cases entered into the commercially insured cost analyses was 6,896, with no additional outlier or diagnostic adjustments performed to preserve a broad population-level analysis. The percentage of cases by procedure for the commercial study period was as follows: RFE=0.93%, NF-OP=14.12%, NF-IP=26.48%, and MEDMGT=58.48%.

Table 1b profiles the patient demographics of each treatment group under review in this commercially insured population of patients. The commercially insured treatment groups were heavily weighted toward females for all therapeutic options except for RFE (only 23% female). RFE had a notably lower percentage of cases in the under 25 and 25–44 age bands combined (RFE=8%, NF-OP=34%, NF-IP=36%, and MEDMGT=30%). The percentage of cases in the NF-OP, NF-IP, and MEDMGT treatment groups was observably less in the 65–69 age band relative to the RFE group (RFE=23%, NF-OP=5%, NF-IP=7%, MEDMGT=8%).

Budget impact analysis

This analysis focused primarily on postprocedure costs and utilization across the five components of care. Preprocedure costs are noted when appropriate to contrast pre- and post-treatment trends or findings. Comparisons of mean allowed costs were made between RFE, NF performed in both the outpatient and inpatient settings (the surgical standard of care) and MEDMGT.

TABLE 1A
Medicare insured – demographics by refractory GERD treatment group

Age band	RFE (%)	NF-OP (%)	NF-IP (%)	MEDMGT (%)	Total (%)
<65	13.0	33.8	33.4	28.5	30.6
65–69	39.1	32.7	31.4	31.8	31.8
70–74	30.4	20.6	20.2	21.0	20.8
75–79	8.7	9.2	10.2	12.1	11.1
80–84	4.3	3.1	3.6	5.0	4.3
85+	4.3	0.6	1.3	1.6	1.4
Total	**100.0**	**100.0**	**100.0**	**100.0**	**100.0**
Female	65.2	70.7	70.9	70.1	70.4
Male	34.8	29.3	29.1	29.9	29.6

Source: Medicare Standard Analytic File (inpatient and outpatient), index procedure year 2012

TABLE 1B
Commercially insured – demographics by refractory GERD treatment group

Age Band	RFE (%)	NF-OP (%)	NF-IP (%)	MEDMGT (%)	Total (%)
<25	1.6	5.5	13.0	3.9	6.5
25–44	6.3	28.7	22.9	25.7	25.2
45–64	57.8	56.0	49.6	54.6	53.5
65–69	23.4	5.1	6.5	8.0	7.3
70–74	3.1	2.2	4.3	3.8	3.7
75–79	1.6	2.2	2.2	2.3	2.3
80–99	6.3	0.3	1.5	1.7	1.5
Total	**100.0**	**100.0**	**100.0**	**100.0**	**100.0**
Female	23.4	61.8	61.5	63.9	62.6
Male	76.6	38.2	38.5	36.1	37.4

Source: Optum Single Payer Database (index procedure years, 2012–2013)[1]
[1] Two years of index data were examined to capture additional cases.

Medicare Population

Tables 2a, 2b, and 2c compare the mean allowed payments for Medicare patients whose refractory GERD was treated with RFE versus those receiving the other treatment options (12 months prior to index procedure, 12 months following the index procedure, and for the entire 24-month tracking period). These tables are supplemented by Table 3, which shows the average utilization per Medicare beneficiary, by component of care, for each time period.

RFE vs. NF-OP: For the 12 months leading up to the referent index procedure, the major cost variance was observed in the average physician service payments (RFE=$4,671.61, NF-OP=$3,553.15). This increased cost difference in physician service utilization of $1,118.47 (31.5%) was the major reason the overall cost of RFE was higher than NF-OP for the preprocedure period ($7,622.60 vs. $7,328.84, a 4.0% difference). Twelve months postprocedure, a nominal savings of $294.28 (4.4%) in total service costs was associated with RFE and was driven primarily by a $1,103.16 (56.7%) reduction in outpatient costs. This savings could be partially attributed to reduced reliance on postprocedure outpatient visits: RFE-treated patients utilized outpatient visits half as often as NF-OP patients (3.7 visits per member vs. 7.9 visits per member). Combining index procedure costs and postprocedure service costs for both groups revealed a 10.0% cost savings ($1,066.93) for RFE.

RFE vs. NF-IP: Average payments for RFE were considerably lower than NF-IP for several key elements of the analysis: estimated preprocedure outpatient costs ($1,487.93 vs. $2,673.91), index procedure costs ($3,200.00 vs. 11,342.75), and average postprocedure outpatient costs ($841.33 vs. $2,449.07). When index-procedure costs were combined with 12-month follow-up costs, RFE-treated patients evidenced reduced payments totaling $9,853.86 (a 50.5% savings over NF-IP). Over the 24-month episode of care, the resultant savings totaled $12,035.42 per case (41.1% reduction) associated with use of RFE in this group of beneficiaries.

RFE vs. MEDMGT: When compared against the MEDMGT group, RFE-treated patients incurred comparable preprocedure pharmacy costs and modestly lower inpatient and emergency room costs. Preprocedure outpatient costs incurred by patients treated with RFE vs. MEDMGT were notably lower ($1,487.93 vs. $2,535.19 respectively), which is likely attributable to a lower outpatient visit rate of 5.5 for RFE versus 9.5 for the MEDMGT treatment group. For the postprocedure period, the differentials in allowed costs per claim favored RFE for all service components other than physician services. When tracked for 24 months, the RFE treatment option had total costs, on average, that were $2,285.84 lower (11.7% savings) than those observed in the MEDMGT treatment group.

Commercially Insured Population

Tables 4a, 4b, and 4c compare the mean allowed payments for commercially insured patients whose refractory GERD was treated with RFE versus those receiving the other treatment options (12 months prior to index procedure, 12 months following the index procedure, and for the entire 24-month tracking period). These tables are supplemented by Table 5, which shows the average utilization per commercially insured beneficiary, by component of care, for each time period.

RFE vs. NF-OP: Patients treated with RFE vs. NF-OP exhibited higher preprocedure costs (RFE=$14,634.17 vs. NF-OP=$12,103.69) and postprocedure service costs (RFE=$14,009.68 vs. NF-OP=$9,421.76). However, when postprocedure service costs were coupled with the index procedure costs, a savings of $2,741.13 (13.4%) was realized for RFE compared to NF-OP. During the postprocedure time frame, RFE was associated with lower utilization per member in emergency room use (0.2 vs. 0.4 visits per member, 50.0% reduction), pharmacy services (10.8 vs. 12.3 scripts per member, 13.9% reduction), and physician services (33.5 vs. 34.9 procedures per member, 4.0% reduction). Moreover, RFE showed a 31.6% reduction in pharmacy prescriptions per member from the preprocedure period to the postprocedure period (15.8 vs. 10.8 scripts), while NF-OP generated only a 12.8% reduction (14.1 vs. 12.3 scripts). On balance, total costs per case during the 24-month episode of care were comparable between RFE and NF-OP (i.e., RFE was $210.65 less costly).

RFE vs. NF-IP: For the preprocedure tracking period, the differences in allowed costs per claim trended in favor of RFE for all service components except outpatient ($4,177.85 greater for RFE). When totaled, however, preprocedure costs for RFE were $2,930.32 (16.7%) lower than NF-IP ($14,634.17 vs. $17,564.49). Average costs for RFE also trended favorably for all service components in the postprocedure period other than outpatient costs ($3,047.69 greater for RFE) compared to NF-IP. Nevertheless, total costs per claims for index procedure and 12-month follow-up care averaged $12,579.12 ($17,703.21 vs. $30,282.33) less for the RFE group than for patients receiving NF-IP treatment, a 41.5% reduction in payments. Total expenditures for the 24-month episode of care were found to be $15,509.44 lower for RFE-treated patients (NF-IP=$47,846.82 vs. RFE=$32,337.38), a 32.4% savings. In both cases, the high cost of an NF-IP procedure contributed to the sizeable observed variances.

Compared to NF-IP, RFE also

TABLE 2A Medicare insured – comparison of average allowed costs per case for RFE vs. treatment options by service component (12 months pre-index procedure)

Service component	RFE ($)	NF-OP ($)	Δ for RFE vs NF-OP ($)	% Δ for RFE vs NF-OP	NF-IP ($)	Δ for RFE vs NF-IP ($)	% Δ for RFE vs NF-IP	MEDMGT ($)	Δ for RFE vs MED-MGT ($)	% Δ for RFE vs MEDMGT
Inpatient[1]	191.04	238.00	(46.95)	–19.7	566.66	(375.61)	–66.3	449.09	(258.05)	–57.5
Outpatient[1]	1,487.93	2,225.71	(737.78)	–33.1	2,673.91	(1,185.98)	–44.4	2,535.19	(1,047.26)	–41.3
Emergency room[1]	68.00	169.09	(101.09)	–59.8	156.56	(88.56)	–56.6	199.63	(131.64)	–65.9
Physician[2]	4,671.61	3,553.15	1,118.47	31.5	5,078.08	(406.47)	–8.0	3,710.89	960.72	25.9
Pharmacy[2]	1,204.02	1,142.90	61.12	5.3	1,328.96	(124.94)	–9.4	1,230.94	(26.92)	–2.2
Total allowed cost per claim	7,622.60	7,328.84	293.76	4.0	9,804.16	(2,181.56)	–22.3	8,125.75	(503.15)	–6.2

[1]Source: Medicare Standard Analytic File (inpatient and outpatient) 2011–2013
[2]Source: Optum Single Payer Database 2011–2014

TABLE 2B Medicare insured – comparison of average allowed costs per case for RFE vs. treatment options by service component (12 months post-index procedure)

Service component	RFE ($)	NF-OP ($)	Δ for RFE vs NF-OP ($)	% Δ for RFE vs NF-OP	NF-IP ($)	Δ for RFE vs NF-IP ($)	% Δ for RFE vs NF-IP	MEDMGT ($)	Δ for RFE vs MED-MGT ($)	% Δ for RFE vs MEDMGT
Inpatient[1]	444.78	416.56	28.22	6.8	839.81	(395.03)	–47.0	2,421.05	(1,976.26)	–81.6
Outpatient[1]	841.33	1,944.49	(1,103.16)	–56.7	2,449.07	(1,607.74)	–65.6	2,851.32	(2,009.99)	–70.5
Emergency room[1]	96.21	188.49	(92.28)	–49.0	166.86	(70.66)	–42.3	196.97	(100.76)	–51.2
Physician[2]	4,129.63	3,155.07	974.56	30.9	3,629.94	499.68	13.8	4,525.91	(396.28)	–8.8
Pharmacy[2]	943.56	1,045.18	(101.62)	–9.7	1,080.92	(137.36)	–12.7	1,111.10	(167.54)	–15.1
Index procedure[3]	3,200.00	3,972.64	(772.64)	–19.4	11,342.75	(8,142.75)	–71.8	331.85	2,868.15	864.3
Total allowed cost per claim	9,655.51	10,722.43	(1,066.93)	–10.0	19,509.37	(9,853.86)	–50.5	11,438.20	(1,782.70)	–15.6

[1]Source: Medicare Standard Analytic File (inpatient and outpatient) 2011–2013
[2]Source: Optum Single Payer Database 2011–2014
[3]Source: Medicare Standard Analytic File (inpatient and outpatient) 2011–2013; RFE is an industry source

TABLE 2C Medicare insured – comparison of average allowed costs per case for RFE vs. treatment options by service component (24 months pre- and post-index procedure)

Service component	RFE ($)	NF-OP ($)	Δ for RFE vs. NF-OP ($)	% Δ for RFE vs. NF-OP	NF-IP ($)	Δ for RFE vs. NF-IP ($)	% Δ for RFE vs. NF-IP	MEDMGT ($)	Δ for RFE vs. MED-MGT ($)	% Δ for RFE vs. MEDMGT
Inpatient[1]	635.83	654.56	(18.73)	–2.9	1,406.47	(770.64)	–54.8	2,870.14	(2,234.31)	–77.8
Outpatient[1]	2,329.26	4,170.20	(1,840.94)	–44.1	5,122.98	(2,793.72)	–54.5	5,386.51	(3,057.25)	–56.8
Emergency room[1]	164.21	357.58	(193.37)	–54.1	323.42	(159.22)	–49.2	396.60	(232.40)	–58.6
Physician[2]	8,801.24	6,708.22	2,093.03	31.2	8,708.02	93.22	1.1	8,236.80	564.44	6.9
Pharmacy[2]	2,147.58	2,188.08	(40.50)	–1.9	2,409.88	(262.30)	–10.9	2,342.05	(194.47)	–8.3
Index procedure[3]	3,200.00	3,972.64	(772.64)	–19.4	11,342.75	(8,142.75)	–71.8	331.85	2,868.15	864.3
Total allowed cost per claim	17,278.11	18,051.27	(773.17)	–4.3	29,313.53	(12,035.42)	–41.1	19,563.95	(2,285.84)	–11.7

[1]Source: Medicare Standard Analytic File (inpatient and outpatient) 2011–2013
[2]Source: Optum Single Payer Database 2011–2014
[3]Source: Medicare Standard Analytic File (inpatient and outpatient) 2011–2013; RFE is an industry source

showed lower utilization per member during the postprocedure period in the categories of pharmacy services (10.8 vs. 11.5 scripts per member, 6.1% lower), outpatient care (2.8 vs. 2.9 visits per member, 4.6% lower) and emergency room use (0.2 vs. 0.6 visits per member, 69.6% lower). It is important to note that this outpatient utilization reduction reinforces that the higher RFE costs noted in this section are driven by higher unit costs. Our review of the data could not determine if these higher unit costs for RFE were the result of higher-intensity services or less desirable contracted rates with the outpatient providers.

RFE vs. MEDMGT: During the postprocedure period, average costs for all service categories (except outpatient care) were lower for patients treated with RFE relative to those in the MEDMGT group. Overall, combined costs of the index procedure and postprocedure care for the RFE treatment group generated costs that were $1,403.57 (7.3%) lower than those observed in the MEDMGT treatment group.

RFE treatment was accompanied by lower service utilization per member in the postprocedure period, compared to MEDMGT, in the categories of pharmacy (10.8 vs. 13.1 scripts per member, 17.6% lower), physician services (33.5 vs. 37.3 procedures per member, 10.2% lower), outpatient care (2.8 vs. 3.4 visits per member, 18.0% lower) and emergency room use (0.2 vs. 0.4 visits per member, 56.3% lower). Figure 1 (page 49) summarizes the cost of 24-month episodes of care for RFE and other treatments.

Sensitivity analysis

Tables 6a and 6b illustrate for the Medicare and commercially insured populations, respectively, the impact on PMPM expenditures of shifting the observed procedure frequency distribution to one where a higher percentage of RFE is assumed. The formulas used to calculate current PMPM costs, projected PMPM costs, and PMPM savings for both the Medicare and commercially insured populations are as follows:

Current PMPM costs=(refractory GERD members * total episode of care cost * current refractory GERD distribution) / member months projected PMPM costs=(refractory GERD members * total episode of care cost * projected refractory GERD distribution) / member months

PMPM savings=projected PMPM – current PMPM

Note: In order to derive an annual PMPM savings, the PMPM costs spanning 24 months were divided by 2.

The sensitivity analyses reflect a modest redistribution to RFE of between 1% and 5% of total cases, with 20% of this volume coming from the MEDMGT treatment option and the remaining 80% coming from the NF-OP and NF-IP treatment options.

Medicare population: The NF allocations were based on a recent Medicare case mix (27.99% from NF-OP and 52.01% from NF-IP). Setting the historic distribution of procedures as the baseline, the estimated PMPM costs of each treatment group were: RFE=$0.06; NF-OP= $3.73; NF-IP=$12.60, and MEDMGT=$16.01. Assuming RFE utilization frequency increases to 1% of the total procedure mix, the overall estimated impact on payer expenditures would be a net savings of $0.14 PMPM. Increasing the RFE adoption percentage to a level at which RFE cases were 5% of total cases performed reduces overall expenditures by $0.69 PMPM.

Commercial population: The NF allocation was based on a recent commercial case mix (27.84% from NF-OP and 52.16% from NF-IP). Setting the historic distribution of procedures as the baseline, the PMPM costs of each treatment option were: RFE=$0.40; NF-OP=$7.07; NF-IP=$19.63, and MEDMGT=$27.38. Assuming RFE utilization frequency increases to 1% of the total procedure frequency, the overall estimated impact on payer expenditures would be a net savings of $0.19 PMPM. Increas-

TABLE 3
Medicare insured – average service utilization per member with refractory GERD (pre- and post-index procedure)

	Pre-procedure average 12-month utilization							Post-procedure average 12-month utilization						
Treatment options	**RFE**	**NF-OP**	**% Δ**	**NF-IP**	**% Δ**	**MED-MGT**	**% Δ**	**RFE**	**NF-OP**	**% Δ**	**NF-IP**	**% Δ**	**MED-MGT**	**% Δ**
Outpatient[1]	5.5	9.1	–39.6	9.5	–42.2	9.5	–42.1	3.7	7.9	–54.1	8.5	–57.0	9.8	–62.6
Emergency room[1]	0.5	1.0	–49.3	0.9	–38.7	1.1	–51.2	0.4	1.1	–64.9	0.9	–55.5	1.0	–62.1

Source: Outpatient Standard Analytical File 2011–2013
[1] Visits per member.
Note: Physician and pharmacy service utilization rates are not available in the Medicare Outpatient Standard Analytic File.

TABLE 4A Commercially insured – comparison of average allowed costs per case for RFE vs. treatment options by service component (12 months pre-index procedure)

Service component	RFE ($)	NF-OP ($)	Δ for RFE vs NF-OP ($)	% Δ for RFE vs NF-OP	NF-IP ($)	Δ for RFE vs NF-IP ($)	% Δ for RFE vs NF-IP	MEDMGT ($)	Δ for RFE vs MED-MGT ($)	% Δ for RFE vs MED-MGT
Inpatient	222.57	221.35	1.22	0.6	1,539.22	(1,316.66)	–85.5	427.75	(205.19)	–48.0
Outpatient	7,186.19	4,984.00	2,202.19	44.2	6,056.03	1,130.16	18.7	4,771.75	2,414.44	50.6
Emergency room	181.87	988.14	(806.27)	–81.6	1,272.46	(1,090.58)	–85.7	1,119.70	(937.83)	–83.8
Physician	5,839.52	4,720.17	1,119.35	23.7	7,316.14	(1,476.62)	–20.2	4,796.64	1,042.88	21.7
Pharmacy	1,204.02	1,190.03	13.99	1.2	1,380.63	(176.61)	–12.8	1,274.42	(70.40)	–5.5
Total allowed cost per claim	14,634.17	12,103.69	2,530.48	20.9	17,564.49	(2,930.32)	–16.7	12,390.27	2,243.90	18.1

Source: Optum Single Payer Database 2011–2014

TABLE 4B Commercially insured – comparison of average allowed costs per case for RFE vs. treatment options by service component (12 months post-index procedure)

Service component	RFE ($)	NF-OP ($)	Δ for RFE vs NF-OP ($)	% Δ for RFE vs NF-OP	NF-IP ($)	Δ for RFE vs NF-IP ($)	% Δ for RFE vs NF-IP	MEDMGT ($)	Δ for RFE vs MED-MGT ($)	% Δ for RFE vs MEDMGT
Inpatient	909.50	517.37	392.13	75.8	1,793.57	(884.07)	–49.3	3,164.13	(2,254.63)	–71.3
Outpatient	6,665.60	2,724.23	3,941.37	144.7	3,617.91	3,047.69	84.2	6,237.43	428.17	6.9
Emergency room	328.99	851.45	(522.46)	–61.4	1,275.28	(946.29)	–74.2	$835.94	(506.95)	–60.6
Physician	5,162.04	4,208.84	953.19	22.6	5,191.60	(29.57)	–0.6	6,054.78	(892.74)	–14.7
Pharmacy	943.56	1,119.87	(176.31)	–15.7	1,154.31	(210.76)	–18.3	1,199.97	(256.42)	–21.4
Index procedure	3,693.53	11,022.58	(7,329.05)	–66.5	17,249.65	(13,556.12)	–78.6	1,614.53	2,079.00	128.8
Total allowed cost per claim	17,703.21	20,444.34	(2,741.13)	–13.4	30,282.33	(12,579.12)	–41.5	19,106.78	(1,403.57)	–7.3

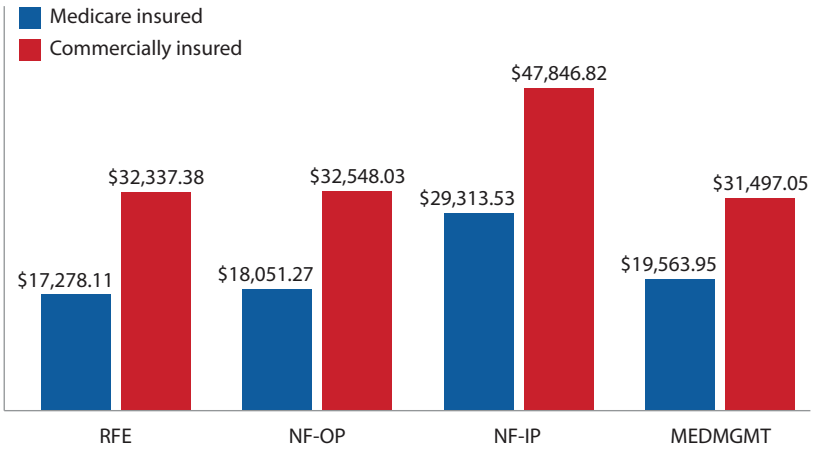
Source: Optum Single Payer Database 2011–2014

TABLE 4C Commercially insured – comparison of average allowed costs per case for RFE vs. treatment options by service component (24 months pre- and post-index procedure)

Service component	RFE ($)	NF-OP ($)	Δ for RFE vs NF-OP ($)	% Δ for RFE vs NF-OP	NF-IP ($)	Δ for RFE vs NF-IP ($)	% Δ for RFE vs NF-IP	MEDMGT ($)	Δ for RFE vs MED-MGT ($)	% Δ for RFE vs MEDMGT
Inpatient	1,132.06	738.71	393.35	53.2	3,332.79	(2,200.73)	–66.0	3,591.88	(2,459.82)	–68.5
Outpatient	13,851.79	7,708.23	6,143.55	79.7	9,673.94	4,177.85	43.2	11,009.18	2,842.61	25.8
Emergency room	510.87	1,839.60	(1,328.73)	–72.2	2,547.74	(2,036.88)	–79.9	1,955.65	(1,444.78)	–73.9
Physician	11,001.55	8,929.01	2,072.54	23.2	12,507.75	(1,506.19)	–12.0	10,851.42	150.14	1.4
Pharmacy	2,147.58	2,309.90	(162.32)	–7.0	2,534.95	(387.37)	–15.3	2,474.39	(326.81)	–13.2
Index procedure	3,693.53	11,022.58	(7,329.05)	–66.5	17,249.65	(13,556.12)	–78.6	1,614.53	2,079.00	128.8
Total allowed cost per claim	32,337.38	32,548.03	(210.65)	–0.6	47,846.82	(15,509.44)	–32.4	31,497.05	840.33	2.7

Source: Optum Single Payer Database 2011–2014

FIGURE 1
Radiofrequency energy compared with other treatments of GERD for 24-month episode of care



Based on results presented in Tables 2C and 4C

ing the RFE percentage to 5% of total cases would yield an overall estimated savings of $0.93 PMPM.

DISCUSSION

GERD is considered a major health issue in the United States and poses a significant health and economic challenge to payers. Given its incidence and complication profile, refractory GERD is a disease process worthy of refined clinical and economic research to fully understand the most effective and efficient ways to manage it. To this end, our study was designed to assist U.S. payers in better understanding the economic implications associated with the four best known treatment options for refractory GERD. Moreover, the primary focus of this study was to provide payers with information on how medical resources are consumed in both Medicare and commercially insured GERD populations on a longitudinal basis. In light of the renewed focus of both CMS and private payers on episode-of-care arrangements, this study offers policymakers, payers, and accountable care entities additional insight into the economic consequences when assessing the treatment options available for this chronic condition. It is also important to emphasize that our study employed a population perspective in that all claims for which a payment was made and that met the basic inclusion criteria (based on the target diagnoses and procedures) were included. We anticipate that this real-world approach will be attractive to U.S. public and private payers.

As our results demonstrate, RFE is an economically favorable choice for payers based on index and post-procedure resource consumption analyses. When considering the index and postprocedure time period, RFE demonstrated a net savings over its comparators in both the Medicare and commercial populations. Of particular note is the favorable impact on ER and pharmacy utilization and costs, where significant reductions on the order of 13% in pharmacy utilization when compared to NF-OP and 70% in ER utilization when compared to NF-IP were observed. Presumably, these reductions were driven by improved symptom profiles in RFE patients that allowed patients and their physicians to avoid ER visits for severe but often transient symptoms, as well as moderate pharmacy costs.

While this cost profile and analysis

TABLE 5
Commercially insured – average service utilization per member with refractory GERD (pre- and post-index procedure)

	Pre-procedure average 12-month utilization							Post-procedure average 12-month utilization						
Treatment options	**RFE**	**NF-OP**	**% Δ**	**NF-IP**	**% Δ**	**MED-MGT**	**% Δ**	**RFE**	**NF-OP**	**% Δ**	**NF-IP**	**% Δ**	**MED-MGT**	**% Δ**
Outpatient[1]	3.3	3.7	–10.0%	4.5	–26.3%	3.6	–8.4%	2.8	2.1	36.9%	2.9	–4.6%	3.4	–17.6%
Emergency room[1]	0.1	0.5	–71.0%	0.7	–78.6%	0.5	–73.8%	0.2	0.4	–56.8%	0.6	–69.6%	0.4	–56.3%
Physician[2]	37.9	35.4	7.2%	44.6	–14.9%	38.8	–2.3%	33.5	34.9	–3.9%	27.1	23.7%	37.3	–10.0%
Pharmacy[3]	15.8	14.1	11.8%	13.6	15.7%	14.0	12.3%	10.8	12.3	–12.6%	11.5	–6.1%	13.1	–18.0%

Source: Optum Single Payer Database 2011–2014
[1] Visits per member.
[2a] Physician services per member. On average, physician services include 4-5 procedures per visit, yielding up to 6-8 visits per year.
[2b] Examples of physician services include injectable administration, EKG interpretation, and pH monitoring.
[3] Prescriptions per member.

TABLE 6A
Medicare insured – sensitivity analysis of impact on PMPM expenditures for members with refractory GERD (index procedure plus 12 months post-procedure)

Distribution	RFE PMPM	NF-OP PMPM	NF-IP PMPM	MEDMGT PMPM	Change in PMPM Post-percentage distribution
Current	$0.0644	$3.7269	$12.6000	$16.0124	N/A
1%	$0.2962	$3.6549	$12.3564	$15.9575	($0.1387)
2%	$0.5279	$3.5829	$12.1129	$15.9026	($0.2774)
3%	$0.7596	$3.5108	$11.8694	$15.8477	($0.4162)
4%	$0.9914	$3.4388	$11.6259	$15.7928	($0.5549)
5%	$1.2231	$3.3668	$11.3824	$15.7379	($0.6936)

Source: Medicare Standard Analytic File (Inpatient and Outpatient) 2011–2013, Optum Single Payer Database 2011–2014

TABLE 6B
Commercially insured – sensitivity analysis of impact on PMPM expenditures for members with refractory GERD (index procedure plus 12 months post-procedure)

Distribution	RFE PMPM	NF-OP PMPM	NF-IP PMPM	MEDMGT PMPM	Change in PMPM Post-percentage distribution
Current	$0.4025	$7.0748	$19.6353	$27.3779	N/A
1%	$0.8363	$6.9354	$19.2483	$27.2843	($0.1863)
2%	$1.2700	$6.7960	$18.8613	$27.1907	($0.3727)
3%	$1.7038	$6.6565	$18.4742	$27.0970	($0.5590)
4%	$2.1375	$6.5171	$18.0872	$27.0034	($0.7453)
5%	$2.5713	$6.3776	$17.7002	$26.9098	($0.9317)

Source: Optum Single Payer Database 2011–2014

of RFE generally kept the Medicare and commercial populations separate (except where data gaps existed), it is worth noting that similar savings trends in the index procedure plus postprocedure periods were observed when RFE was compared to all treatment groups. Accordingly, this investigation likely has identified some consistent and generalizable trends across multiple patient populations, treatment interventions and care components.

Finally, from an economic standpoint, this study has detailed the favorable impact of incremental migration from current surgical and medical options to RFE at various levels that should be considered reasonable and achievable, particularly given the procedure's safety and efficacy profile and its inclusion in SAGES treatment guidelines. Notably, RFE is positioned as an option for those patients who are not getting relief from PPIs and are also not good surgical candidates, a group that represents approximately 20% of the total GERD population. Moreover, RFE is emerging as the only option for patients with GERD after bariatric surgery, offering a welcome relief to a patient cohort that often exhibits GERD symptoms but previously had limited options to address them. Thus, RFE is an important option for addressing an existing treatment gap in the continuum of GERD, and this research lays out its estimated economic value as a complement to its clinical utility.

Few studies are without limitations. While this research offers economic stakeholders a viable framework for evaluating technologies like RFE, several points should be considered when interpreting the results. First, our data sources presented challenges defining the study treatment groups, which solely relied on claims coding. For example, there could be refractory GERD patients who did not fall into any of the four categories, specifically those who did not undergo RFE, fundoplication, or manometry, and whose costs might have affected the results of this analysis, if included. Second, with regard to the commercial and Medicare claims sets utilized, while the membership of both populations was large and national in scope, the results reported in this study may not accurately reflect the

experience of health plans serving smaller, regional populations. To this end, the authors encourage plans to use the structure of this analysis in conjunction with their own data to generate plan-specific results. Third, elongating the postprocedure tracking period to more than 1 year, along with limiting all of the cost categories in the analysis to GI-related procedures and diagnoses could be useful in further research. Fourth, while the structure of our analysis may imply that RFE is a strict substitute for GI surgical interventions, it should be noted that in rare cases, Nissen fundoplication can occur subsequent to RFE if the patient's symptoms do not resolve within a few months after the procedure. Finally, since RFE is emerging as the best option for patients who suffer from GERD after bariatric surgery, an analysis that focuses on just the costs associated with bariatric GERD patients would be of increasing interest to payers as they determine the best course of treatment for this growing patient population.

CONCLUSION

In this era of health reform where key stakeholders are preparing to manage episodes of care governed by risk-based contracting with a focus on population health, budget impact modeling can be useful in evaluating the most efficient ways to manage a chronic and costly condition, such as refractory GERD. Although by no means a new technique, RFE is an important and cost-efficient procedure that fills an important treatment void for GERD patients not getting relief from PPI use. Payers and providers should carefully consider the results of this study when reviewing options for their GERD patients: RFE offers both stakeholders another tool for more effectively managing patients with GERD under value-based care arrangements and population health strategies.

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Funding source: Mederi Therapeutics (Norwalk, Conn.)

Conflict disclosures: David Gregory and Daniel Buck are employees of Baker Tilly LLP, New York, N.Y. Dennis J. Scotti is a part-time consultant at Baker Tilly LLP. Baker Tilly LLP is a paid consultant to Mederi as a technical advisor and receives indirect support from Mederi for secondary database acquisition. George Triadafilopoulos is a consulting clinical advisor to Mederi Therapeutics.

Acknowledgements: Keith Needham, consultant, Baker Tilly LLP

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