

- Sirikan Rojanasart and Stacey Amorosi are full-time employees of Boston Scientific.
- Bilal Chughtai and Neal Shore are paid clinical consultants to Boston Scientific.
- Kurt Neeser, Dmitry Gulyaev, Manica Agrawal, and Michael Minshall contributed to this work as employees of Certara.
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MEDICARE BUDGET IMPACT ANALYSIS OF CONVECTIVE WATER VAPOR ENERGY THERAPY COMPARED TO PROSTATIC URETHRAL LIFT FOR TREATMENT OF BENIGN PROSTATIC HYPERPLASIA

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Background – Benign Prostatic Hyperplasia (BPH)

- A highly prevalent health condition among men, costing US Medicare over \$1 billion annually.¹
- Associated with lower urinary tract symptoms (LUTS), including voiding and storage problems.²
- Patients with moderate-to-severe LUTS often begin with pharmacotherapy, however, adherence is low due to daily dosing and adverse events.³
- Minimally invasive surgical treatment options exist for men with moderate-to-severe LUTS:
 - Water vapor energy therapy (WAVE; Rezum™ System, Boston Scientific, Marlborough, MA)
 - Prostatic urethral lift (PUL; UroLift® System, NeoTract, Pleasanton, CA)

1) Litwin MS et al. Urologic diseases in America. National Institute of Diabetes and Digestive and Kidney Diseases. Washington, DC: US Government Printing Office, 2012; NIH Publication No.12-7865 [pp. 468].

2) McVary KT, et al. Rezum water vapor thermal therapy for lower urinary tract symptoms associated with benign prostatic hyperplasia: 4-year results from randomized controlled study. *Urology*. 2019;126:171-179.

3) Zabkowski T, Saracyn M. Drug adherence and drug-related problems in pharmacotherapy for lower urinary tract symptoms related to benign prostatic hyperplasia. *J Physiol Pharmacol*. 2018;69(4).

Objective

The objective of this study was to assess the budget impact to Medicare of WAVE versus PUL using long-term clinical outcomes from the Rezum II and LIFT randomized controlled trials.

Methods – WAVE and PUL Trials Had Similar Study Designs

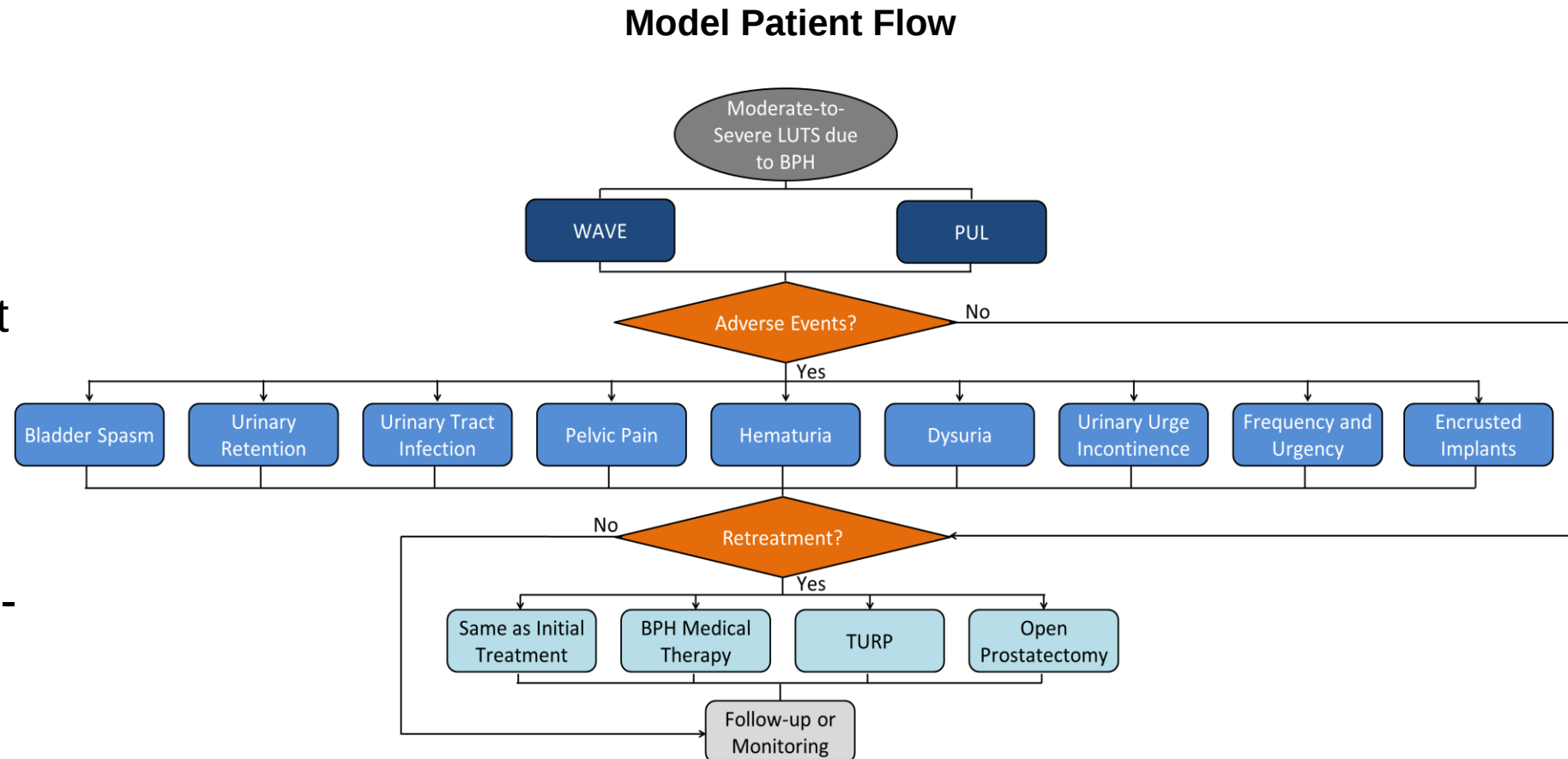
		Rezum II – WAVE ¹	LIFT - PUL ²
Study Design	Randomized Controlled Trial (RCT)	✓	✓
	Sham Control	✓	✓
	Sample Size (Intervention : Control)	136 : 61	140 : 66
	Centers	15 US centers	19 US, AUS, CAN centers
Key Inclusion Criteria	At Least 50 Years	✓	✓
	Symptomatic BPH	✓	✓
	International Prostate Symptom Score (IPSS) ≥ 13	✓	✓
	Prostate Volume 30 – 80 cc	✓	✓
Baseline Characteristics of Treatment Arm	Mean Age (SD)	63.0 (7.1)	67 (8.6)
	Mean IPSS (SD)	22.0 (4.8)	22.2 (5.4)
	Mean Prostate Volume (SD)	45.8 (13.0)	44.5 (12.4)

1) McVary KT, et al. Minimally invasive prostate convective water vapor energy ablation: A multicenter, randomized, controlled study for the treatment of lower urinary tract symptoms secondary to benign prostatic hyperplasia. *J Urol*. 2016;195(5):1529-1538.

2) Roehrborn CG, et al. The prostatic urethral lift for the treatment of lower urinary tract symptoms associated with prostate enlargement due to benign prostatic hyperplasia: The L.I.F.T. study. *J Urol*. 2013;190(6):2161-2167.

Methods – Model Overview

- Developed an Excel-based budget impact model from a US Medicare perspective.
- Populated with a cohort of males with a mean age of 63 and an average IPSS of 22.
- Compared average per-patient costs over a 4-year time period.



Methods – Clinical Data

- Clinical data were derived from the Rezum II^{1,2} and LIFT^{3,4} randomized controlled trials at 4 years of follow up.
- Clinical inputs included IPSS, procedural- and LUTS-related adverse events (AEs) and retreatment rates.
- WAVE¹ and PUL³ AEs were obtained for 0-3 and 4-12 months.
- Retreatment rates were calculated from the Rezum II^{1,2} and LIFT^{3,4} CONSORT diagrams using life table survival analysis.

1) McVary KT, et al. Minimally invasive prostate convective water vapor energy ablation: A multicenter, randomized, controlled study for the treatment of lower urinary tract symptoms secondary to benign prostatic Hyperplasia. *J Urol*. 2016;195(5):1529-1538.

2) McVary KT, et al. Rezum water vapor thermal therapy for lower urinary tract symptoms associated with benign prostatic hyperplasia: 4-year results from randomized controlled study. *Urology*. 2019;126:171-179.

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4) Roehrborn CG, et al. Five year results of the prospective randomized controlled prostatic urethral L.I.F.T. study. *Can J Urol*. 2017;24(3):8802-8813.

Methods – Clinical Inputs

	WAVE		PUL	
	0-3 Months	4-12 Months	0-3 Months	4-12 Months
Adverse Events				
Bladder Spasm	NA	NA	3.6% ³	0.7% ³
Urinary Retention	3.7% ¹	0.0% ¹	0.7% ³	0.7% ³
Urinary Tract Infection	3.7% ¹	0.0% ¹	2.9% ³	0.0% ³
Pelvic Pain	2.9% ¹	0.0% ¹	17.9% ³	1.4% ³
Hematuria	11.8% ¹	0.0% ¹	25.7% ³	0.7% ³
Dysuria	16.9% ¹	0.7% ¹	34.3% ³	0.7% ³
Urinary Urge Incontinence	0.0% ¹	0.0% ¹	3.6% ³	0.7% ³
Frequency and Urgency	5.9% ¹	0.0% ¹	7.1% ³	2.1% ³
Removal of Encrusted Implants	NA	NA	1.8% ³	5.4% ³
Catheterization	90.4% ¹		51.4% ³	
Retreatment Type				
WAVE	15.4% ²		NA	
PUL	NA		21.9% ⁴	
BPH Medical Therapy	53.8% ²		40.6% ⁴	
TURP*	23.1% ²		37.5% ⁴	
Open Prostatectomy	7.7% ²		0.0% ⁴	

*TURP, Transurethral resection of the prostate

1) McVary KT, et al. Minimally invasive prostate convective water vapor energy ablation: A multicenter, randomized, controlled study for the treatment of lower urinary tract symptoms secondary to benign prostatic Hyperplasia. *J Urol.* 2016;195(5):1529-1538.

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Methods – Cost Inputs

- Procedural, AE, retreatment and follow-up costs were based on 2019 Medicare national payment rates.¹
- Medication costs were obtained from 2017 Medicare Part D Drug Spending² and inflated to 2019 USD.³
- 73% of procedures occurred in office settings and 27% in ambulatory surgical centers.⁴
- Post-operative global payment periods differed between WAVE (90 days) and PUL (0 day).⁵

1) Centers for Medicare & Medicaid Services. FY 2019 IPPS final rule home page. Accessed May 2020.

2) Centers for Medicare & Medicaid Services. Medicare part D drug spending dashboard & data. Accessed May 2020.

3) Bureau of Labor Statistics. CPI for all urban consumers. Accessed May 2020.

4) Data on file at Boston Scientific.

5) Centers for Medicare & Medicaid Services. Global surgery booklet. Accessed May 2020.

	Costs	Codes and Descriptions
Treatment		
WAVE	\$1,689	CPT 53854 ¹
PUL	\$5,617	CPT 52441, 52442; HCPCS C9740 ¹
BPH Medical Therapy	\$415	Office visit (CPT 99213) ¹ ; tamsulosin 40 mg once daily ^{2,3}
TURP	\$4,793	CPT 52601; DRG 714 ¹
Open Prostatectomy	\$7,511	CPT 55821; DRG 667 ¹
Office Visit	\$75	CPT 99213 ¹
Catheterization	\$75	CPT 99213 ¹
Adverse Events		
Bladder Spasm	\$91	Office visit (CPT 99213) ¹ ; oxybutynin 5mg once daily for 14 days ^{2,3}
Urinary Retention	\$150	Two office visits (CPT 99213) ¹ ; 1-week catheterization
Urinary Tract Infection	\$83	Office visit (CPT 99213) ¹ ; cotrimoxazole 800 mg/160 mg 2 times/day for 14 days ^{2,3}
Pelvic Pain	\$82	Office visit (CPT 99213) ¹ ; ibuprofen 400 mg 4 times/day for 14 days ^{2,3}
Hematuria	\$75	Office visit (CPT 99213) ¹
Dysuria	\$119	Office visit (CPT 99213) ¹ ; phenazopyridine 200 mg 3 times/day for 10 days ^{2,3}
Urinary Urge Incontinence	\$91	Office visit (CPT 99213) ¹ ; oxybutynin 5mg once daily for 14 days ^{2,3}
Frequency and Urgency	\$91	Office visit (CPT 99213) ¹ ; oxybutynin 5mg once daily for 14 days ^{2,3}
Encrusted Implant	\$3,201	CPT 52318 ¹

CPT® is a registered trademark of the American Medical Association.; The generic version of medications were considered.

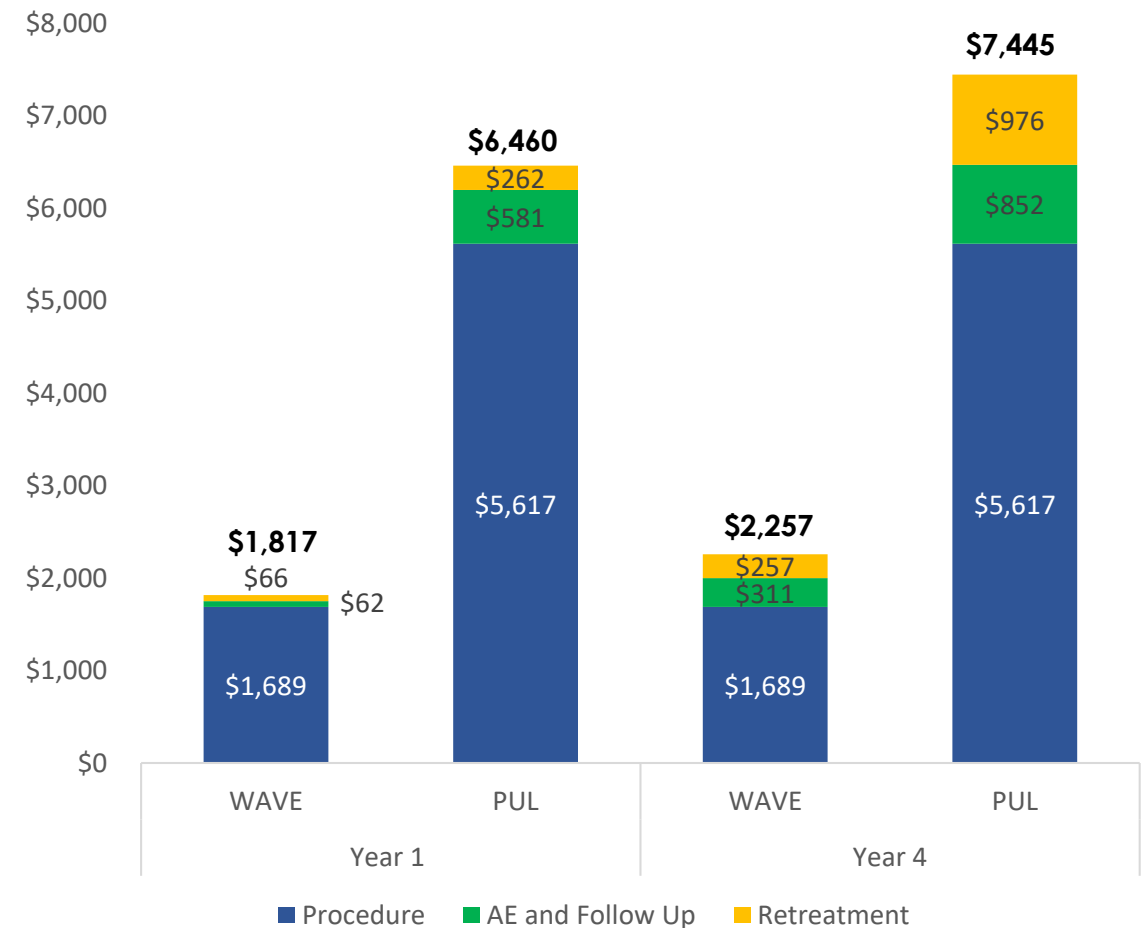
Methods – Sensitivity & Scenario Analyses

- One way sensitivity analysis (OWSA) was conducted to assess the impact of parameter uncertainty on model results by varying all model inputs by $\pm 10\%$.
- Scenario analyses were performed to explore the impact of different post-operative global payment periods for WAVE (90 days) and PUL (0 day).

Results – Base Case

- WAVE procedural costs (which included 90-day follow-up and AE costs) were substantially lower than PUL (\$1,689 vs \$5,617).
- At 4 years, WAVE had lower retreatment rates (10.9% vs 24.6%) and lower total costs (\$2,257 vs \$7,445) than PUL.
- The 70% cost difference was predominantly driven by lower WAVE procedural (\$1,689 vs \$5,617) and retreatment (\$257 vs \$976) costs.

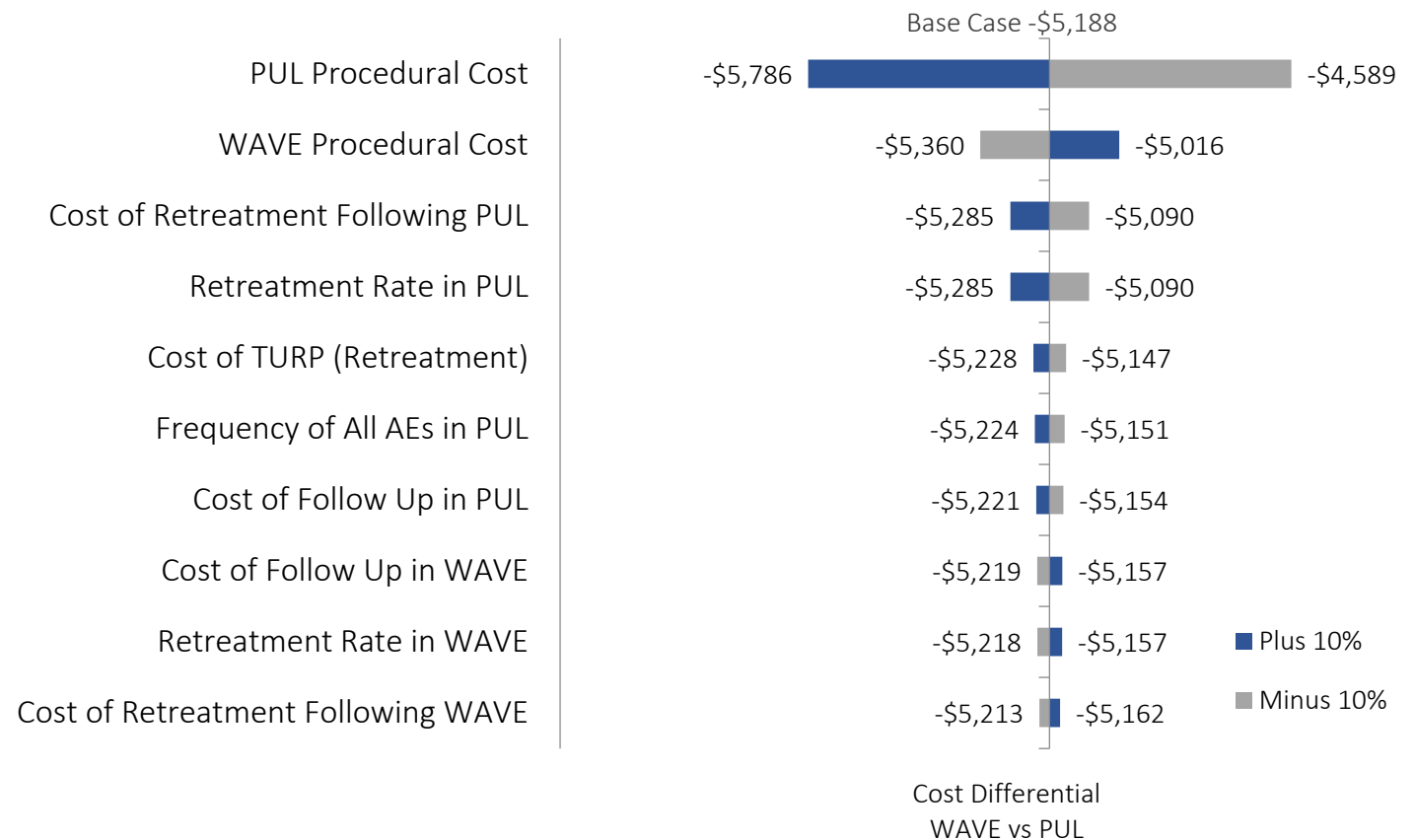
Medicare Per Patient Costs at Year 1 and Year 4



Results – OWSA

- WAVE remained cost saving relative to PUL when model parameters were varied by $\pm 10\%$.
- Among the clinical and cost parameters, the most impactful were:
 - PUL procedural cost
 - WAVE procedural cost
 - Cost and rate of retreatment following PUL

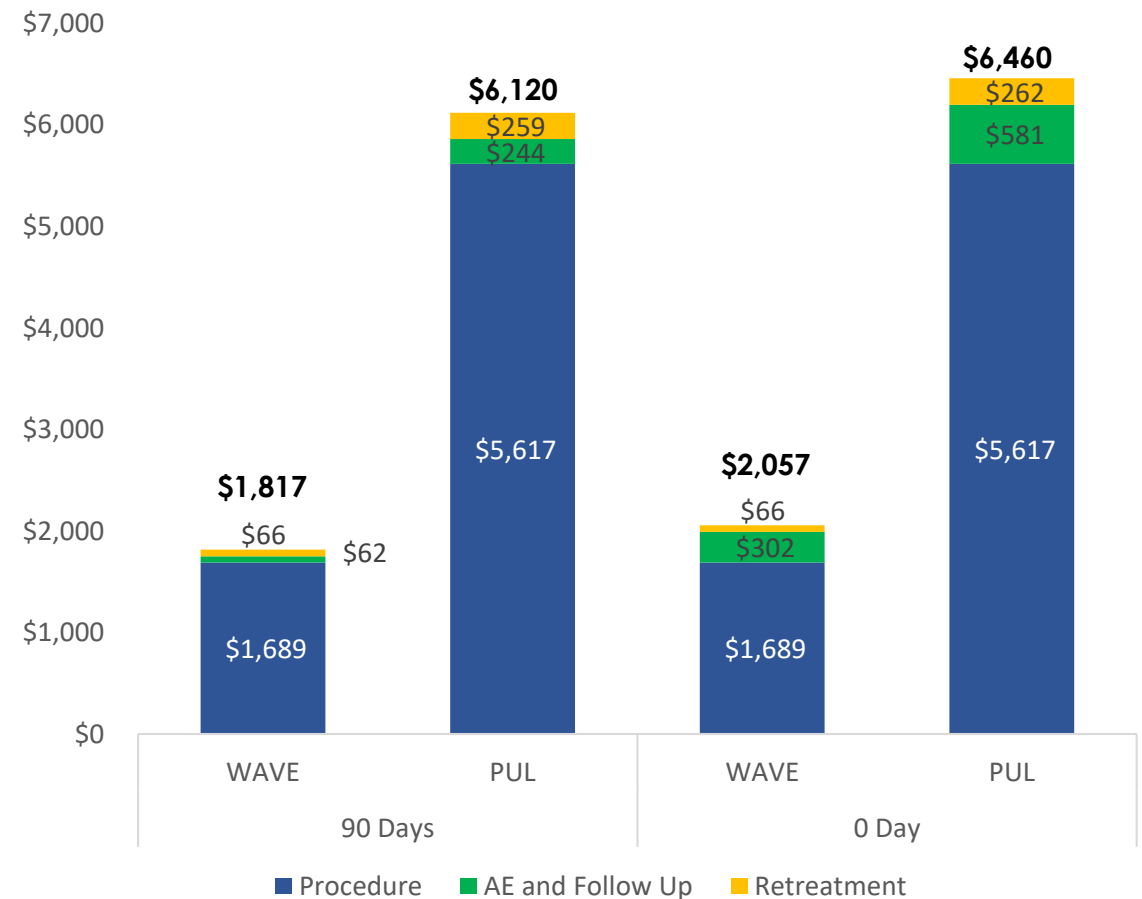
Tornado Diagram at Year 4



Results – Scenario Analyses

- WAVE costs for AEs and follow-up care *increased* from \$62 to \$302 with a 0-day global period.
- PUL costs for AEs and follow-up care *decreased* from \$581 to \$244 with a 90-day global period.
- WAVE total costs at 4 years remained substantially lower than PUL regardless of the global payment period:
 - \$2,497 vs \$7,445 with a 0-day global period
 - \$2,257 vs \$7,099 with a 90-day global period

**Medicare Per Patient Costs at 1 Year:
Global Payment Period Scenarios**



Limitations

- Analyses were based on an indirect comparison of the Rezum II and LIFT trials as no clinical study has directly compared WAVE to PUL.
- Patient outcomes achieved in clinical practice may be different than those achieved in controlled trials.
- Further research is needed to understand the budget impact of WAVE relative to other BPH treatment options.

Conclusions

- WAVE is less costly than PUL to Medicare for the treatment of BPH patients with moderate-to-severe LUTS.
- The cost savings of WAVE compared to PUL were due primarily to lower procedural and retreatment costs.
- These findings provide compelling evidence for clinicians, payers and policy makers to help differentiate minimally invasive surgical treatments for BPH.

Contact Information

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