Examination of the Two-Year US Commercial Payer Budget Impact (BI) of the Leva Pelvic Health System, a prescription medical device that provides supervised pelvic floor muscle training (PFMT) as First-Line Treatment for Female Urinary Incontinence (UI)

Introduction/Abstract

- •Urinary incontinence (UI) affects over 60% of adult women, with 9.8% experiencing daily and 32.4% experiencing monthly symptoms.
- •UI leads to reduced quality of life and increased healthcare costs due to its impact on well-being and social functioning.
- •This study assessed the 24-month budget impact (BI) of treating UI in a 1million member US commercial health plan.
- •We compared clinical practice using the Leva Pelvic Health System to current clinical practice without Leva.



Objectives

- •This study analyzed the 24-month budget impact (BI) of urinary incontinence (UI) treatment in adult women enrolled in a 1-million member US commercial health plan (CHP).
- •We compared current clinical practice using the Leva Pelvic Health System (supervised PFMT at home) versus standard care without Leva (CCP).



Product/Technology

- •Leva is an FDA-approved prescription device that combines motion-based, multi-sensor technology in an intravaginal probe with integrated software for pelvic floor muscle training (PFMT).
- It is designed for at-home use, twice daily, by a single user and provides real-time feedback if motions are performed incorrectly (e.g., bearing down).
- •Clinical evidence supports Leva's superiority over traditional PFMT in patients with stress and mixed urinary incontinence (UI).



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Materials/Methods

- with Leva and 85% on CCP, versus 100% CCP.
- applied to Medicare rates based on Congressional Budget Office data for hospital and physician services. Leva adoption (15%; range: 10–20%), and % of women seeking UI treatment (33%; range: 28–38%).

Budget Impact Model for Urinary Incontinence Treatment

Stress UI Patient Population Count	Incontinence Treatment Adoption	Urge UI Patient Population Count	
60,621	Prevalence of specific UI subtype among women in plan	34,646	
20,005	UI patients currently seeking medical treatment	11,433	
40,616	Number of patients that remain untreated	23,213	

Stress UI Historical SoC% and SoC% with Leva



	Stress UI Historical SoC	Stress UI SoC with Leva		Urge UI Historical SoC	Urge UI SoC with Leva
Unsupervised PFMT	7% (1,400)	7% (1,400)	Unsupervised PFMT	8% (915)	8% (915)
PFPT	1.3% (260)	1.3% (260)	PFPT	1.3% (149)	1.3% (149)
Medications	67.4% (13,483)	55% (11,003)	Medications	80.7% (9,227)	68% (7 <i>,</i> 775)
Pessary	1.3% (260)	1.3% (260)	Surgery	6% (686)	3.7% (423)
Surgery	21% (4,201)	18.4% (3,681)	Botox	2% (229)	2% (229)
Periurethral bulking agents	2% (400)	2% (400)	Neuromodulation/stimulation	2% (229)	2% (229)
PFMT with Leva	0% (0)	15% (3,001)	PFMT with Leva	0% (0)	15% (1,715)

- with Leva.
- \$39.45M at 20% adoption).
- over 24 months.



•A budget impact (BI) model estimated 24-month costs for women receiving first-line PFMT, comparing two cohorts: 15% using CP

•Costs per treated patient and per-member-per-month (PMPM) were calculated using published literature; a 1.5x multiplier was •One-way sensitivity analysis tested key variables: Leva efficacy (61%; range: 44–74%), Leva cost (\$2,160; range: \$1,860–\$2,460),

Urge UI Historical SoC% and SoC% with Leva



Results Part I

•The total estimated 24-month cost per treated patient was \$11,267 for CCP and \$10,447 for CP with Leva, indicating cost savings

•One-way sensitivity analyses showed robust savings, most sensitive to Leva adoption rate (ranging from \$12.11M at 10% to

•Leva remained cost-saving across ranges of efficacy (44–74%: \$19.16M–\$30.85M) and price (\$1,860–\$2,460: \$27.48M–\$24.09M)

	Low	Base	High	One Way Sensitivity Analysis Cost Savings in Millions		
	\$1860	\$2160	\$2460	24.09M	27.48M	
	44%	61%	74%	19.16M	30.85M	
nts	28%	33%	38%	21.88M	29.69M	
า	10%	15%	20%	12.11M		39.45M



Results Part II

- •The 24-month total cost of UI treatment was \$354.2M for the CCP group vs. \$328.4M for the CP with Leva group, yielding \$25.78M in savings, or \$1.07 PMPM.
- •The largest savings came from reductions in surgery (\$17.27M) and medications (\$8.51M).
- •Additional nominal savings were seen in periurethral bulking agents and neurostimulation, due to their lower frequency of use.

Cost of Current Clinical Practice Without Leva and With Leva at 1M Member Plan Over 24 Months



Current Clinical Practice Clinical Practice with Leva Without Leva

□ Initial Treatment Costs □ Advanced Treatment Costs

Conclusion

Access to first-line Leva therapy can reduce two-year **UI treatment costs compared to CCP**

- •Urinary incontinence (UI) in adult females is an underrecognized condition with significant consequences for patients and high costs to health plans.
- Guideline-based first-line PFMT, like Leva therapy, can improve outcomes and reduce progression to invasive, costly interventions—supported by evidence from RCTs and real-world experience.
- •Our 24-month budget impact model shows that the cost of Leva as a first-line option is offset by substantial savings from reduced use of expensive UI treatments.

References/Acknowledgements

Complete references can be found in the attached manuscript Sponsored by Manuscript



