

# Cost Comparison Between Home Biofeedback using PeriCoach® and Supervised Pelvic Floor Muscle Training.

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## Executive Summary

Supervised pelvic floor muscle therapy (PFMT) is already proven to be the most cost effective non-surgical treatment for stress urinary incontinence (SUI) and mixed urinary incontinence (MUI)<sup>1,2</sup>. Biofeedback further improves therapeutic success with a 2011 Cochrane review finding participants receiving biofeedback were significantly more likely to report that their urinary incontinence (UI) was cured or improved compared to those who received PFMT alone (risk ratio 0.75 , 95% confidence interval 0.66 to 0.86)<sup>3</sup>. A recent randomized controlled trial concluded that the PeriCoach® biofeedback system with no formal instruction is non-inferior to PFMT under the supervision of a physical therapist, making this system the most cost-effective form of treatment for SUI and MUI<sup>4</sup>.

The PeriCoach system combines a novel pelvic floor training sensor (using a perineometer with force and movement sensors) with a smartphone application to provide guidance via biofeedback for women with pelvic floor disorders. The silicone coated sensor measures direct muscle contraction, transmitting data via Bluetooth® to a secure smartphone application that provides graphical biofeedback of the contraction force and technique over time. Using this information, women are able to engage the correct muscles, strengthening the pelvic floor<sup>4</sup>. In the United States, the PeriCoach system is available over the counter (OTC) and has obtained FDA 510(k) clearance for the treatment of stress, urge and mixed incontinence in women<sup>5</sup>. Worldwide, PeriCoach has Australian and European regulatory clearances for treatment of urinary incontinence and pelvic organ prolapse and is considered a Class I (lowest risk) medical device.

In a randomized controlled trial of 54 women with SUI or MUI, the PeriCoach system was compared to formal PFMT. Use of the PeriCoach system (without any formal instruction by a pelvic floor physical therapist) was found

to be non-inferior to physiotherapy guided PFMT for the treatment of urinary incontinence based on the International Consultation on Incontinence Questionnaire short form [-4.73 (-3.21--6.25) vs -3.95 (-2.21--5.70), p=0.009]<sup>4</sup>. Additionally, both incontinence severity as measured by the Incontinence Severity Index and Modified Oxford scores (measuring pelvic floor strength) improved significantly<sup>4</sup>. Although not statistically significant, sexual function improved in women who used the PeriCoach system, and mean scores on the Female Sexual Function Index improved from sexual dysfunction range (<26) to normal sexual function (>26) after therapy<sup>4</sup>.

Although the PeriCoach system is non-inferior to supervised PFMT for the treatment of urinary incontinence, the treatment is much less expensive. The PeriCoach system is priced at \$299 in United States dollars (USD) as a one-time cost, while supervised PFMT costs from \$75-500 per session, with therapists recommending up to 16 sessions depending on the severity of incontinence and response to treatment<sup>3,6</sup>. If biofeedback is utilized during PFMT sessions, the cost of care is even higher. The PeriCoach system significantly improves the frequency and severity of stress and mixed urinary incontinence and increases pelvic floor contraction strength without the cost of supervised PFMT.



# Introduction

## Scope of the Problem

Urinary incontinence (UI) in women is a common condition that is detrimental to quality of life<sup>7,8</sup>. Large national studies in the United States and Australia estimate that urinary incontinence affects approximately 30% of all women, with prevalence increasing to 55% by the eighth decade<sup>9,10</sup>. By 2030, 4.4 million or 30% of all Australian women will suffer from urinary incontinence and this rate is estimated to rise as the population ages<sup>10</sup>. This involuntary leakage of urine is most commonly caused by stress urinary incontinence (SUI- defined as the involuntary loss of urine with physical exertion or with sneezing or coughing) or mixed urinary incontinence (MUI- defined as involuntary SUI is the most common type of UI in younger women with pregnancy and vaginal delivery considered major risk factors<sup>12,13</sup>. Up to 75% of women develop SUI and MUI during pregnancy and 30% develop persistent UI immediately after delivery<sup>13,14</sup>. Some women who have injuries to the pelvic floor are able to compensate by using other pelvic floor muscles and behavioral techniques to avoid urine leakage for years, but later develop pelvic floor disorders including UI after menopause due to muscle atrophy and hormonal changes of the vagina and urethra<sup>15</sup>. UI is associated with a higher risk of recurrent urinary tract infections, skin rashes, ulcers, and aside from the physical problems, UI also causes isolation, embarrassment and impairs sexual relationships<sup>15-17</sup>. Despite the financial and emotional burden, many women perceive SUI as an unavoidable result of aging and are not aware that treatment options are available<sup>7</sup>.

## The Cost

The cost of treating and managing UI in women is staggering in both direct and indirect expenses<sup>10,18,19</sup>. When adjusted for inflation, the United States spends an estimated 20 billion dollars annually on female incontinence, and much of this burden falls on the patient<sup>19</sup>. Independent of the medical cost of care, the average woman with UI spends approximately \$1,136 USD per year on incontinence pads, diapers, laundry costs, and costs associated with seeking care from healthcare providers<sup>19</sup>. In Australia, 80% of people with urinary incontinence are women and the estimated total cost of UI is AUD\$42.9

billion, or AUD \$9,014 per person with incontinence<sup>10</sup>. Half of this cost is due to loss of productivity alone<sup>10</sup>. As the population ages and life expectancies lengthen, caring for women with incontinence will only become more expensive and important to treat.

## Treatment

Therapies for SUI and MUI include both surgical and non-surgical treatment options. The most commonly recommended nonsurgical option is pelvic floor muscle therapy (PFMT) which requires a clinician to guide a patient through pelvic floor exercises (also called Kegel Exercises) using instruction and sometimes biofeedback<sup>20,21</sup>. PFMT is

*Compared to other common non-surgical and surgical options for the treatment of SUI and MUI, supervised PFMT has been shown to be the most cost-effective and is recommended as first-line therapy for SUI<sup>2,31</sup>*

recommended as first line therapy for SUI by the American Urogynecologic Society (AUGS), American College of Physicians, and the International Urogynecological Association (IUGA), and the Continence Foundation of Australia before

considering surgical intervention<sup>20-24</sup>. A 2018 Cochrane review concluded that PFMT was 8 times more likely to result in a cure of incontinence compared to no treatment (56% versus 6%; risk ratio (RR) 8.38)<sup>21</sup>. A majority (74%) of women receiving PFMT reported improvement or cure and lost significantly less urine on pad test after treatment compared to no intervention<sup>21</sup>. Women in these groups were also more satisfied with treatment and had better sexual outcomes<sup>21</sup>. Many women prefer PFMT as they would like to avoid surgery due to desire for future pregnancies, health concerns precluding surgery, or preference for non-surgical management for this condition<sup>25,26</sup>.

Contracting the correct pelvic floor muscles is vital for successful treatment of SUI and MUI, but over 30% of women have difficulty isolating these muscles<sup>27,28</sup>. Since almost one in three women are unable to engage their pelvic floor muscles to correctly perform these exercises, many providers use feedback by digital palpation and verbal instruction or biofeedback to give women real time information on exercise quality<sup>3</sup>. Biofeedback uses either vaginal or anal devices to measure the amount of force applied or electrical activity of the muscle<sup>3</sup>. This information is relayed back to the woman using a visual display, sound, or vibration<sup>3</sup>. The use of biofeedback can augment the efficacy of supervised PFMT. A 2011 Cochrane review showed that participants receiving

biofeedback were significantly more likely to report that their UI was cured or improved compared to those who received PFMT alone (risk ratio 0.75, 95% confidence interval 0.66 to 0.86)<sup>3</sup>. PFMT with biofeedback is also effective in postmenopausal and elderly women for the treatment of SUI<sup>29,30</sup>.

*By allowing more women to avoid the risks of surgery, complications of vaginally inserted mesh, and the cost of intervention, the PeriCoach system could provide significant savings while improving the quality of life and productivity for millions of women*

Compared to other common non-surgical and surgical options for the treatment of SUI and MUI, supervised PFMT has been shown to be the most cost effective and is recommended as first line therapy for SUI<sup>2,31</sup>. Preliminary results were presented at the 2019 AUGS/IUGA combined meeting and concluded that PFMT was the most effective non-surgical treatment for SUI based on quality-adjusted-life-years and the least expensive treatment at \$1,241 USD<sup>31</sup>. Aside from surgical implantation of mesh midurethral slings, PFMT is the only cost-effective strategy for SUI<sup>31</sup>. The ongoing use of midurethral sling mesh for UI has been questioned in the last few years and the United Kingdom has banned this procedure until further studies are completed<sup>32</sup>. Similar macroporous polypropylene meshes used for the treatment of pelvic organ prolapse have been banned or removed from use in several countries around the world due to problems with chronic postoperative pain, mesh exposure and infections<sup>32,33</sup>. Due to these concerns, many women and providers prefer non-surgical therapy for SUI.

## The Barrier Problem

Although PFMT is the preferred first line therapy for SUI in all age groups, many women who suffer from the condition have a lack of access to treatment<sup>34</sup>. Barriers exist for women who live far from a facility with a PFMT provider, do not know that treatment is available, have restrictions on their time (such as after the birth of a child), or are unable to take off time from work<sup>35-37</sup>. A recent study found that many patients would prefer to perform PFMT at home due to the cost of co-pays for PFMT, difficulty scheduling, and the distance needed to travel to receive care<sup>4</sup>.

People living in rural areas experience health disparity and have a disproportionate burden of travel to receive

specialized health services<sup>38</sup>. Women who travel longer distances tend to choose costly surgical interventions for the treatment of SUI over non-surgical options (OR 1.45 [1.18-1.76])<sup>39</sup>. This finding is likely due to the requirement of multiple visits to a physical therapist or for pessary fittings. Lack of time is a common cause of non-adherence to PFMT and one large study found that only 42% of women initiating a PFMT training program complete the program<sup>40</sup>. Additionally, costs of insurance copayment, transportation, and time off work are important factors in low PFMT engagement, as having insurance coverage is a predictor that women will participate in PFMT<sup>36</sup>. The ability to perform high quality PFMT at home using a personal biofeedback device may offer more opportunities to treat women who are unable to access PFMT due to cost or distance from providers.

## The Home Biofeedback Solution



Figure 1: PeriCoach System and Packaging

The PeriCoach™ system combines a novel vaginal sensor that functions as a perineometer that connects to a Smartphone application (app) via Bluetooth, providing real time biofeedback to patients for the purpose of pelvic floor rehabilitation. The patient-friendly Smartphone app is linked to a secure web portal, connecting patients with providers. A structured exercise program allows patients to achieve levels of proficiency. To improve compliance, the Smartphone app regularly sends exercise reminders to the patient, and providers can monitor adherence and remotely encourage patients. This system has been proven to have similar efficacy in treating SUI and MUI compared to traditional pelvic floor muscle therapy (PFMT) taught by a professional pelvic floor physical therapist<sup>4</sup>. Additionally, the PeriCoach system allows ongoing feedback technique at home (Figure 2), reinforcing the difficult to learn techniques that are classically taught by physiotherapists.

## Clinical Outcomes

The PeriCoach system has been proven to be effective for the treatment of both SUI and MUI. A multicenter Australian trial randomized 51 women to 20 weeks of PFMT alone versus PFMT combined with home biofeedback with a now-superseded version of the PeriCoach system<sup>41</sup>. This trial demonstrated greater improvement in QOL related to UI when home biofeedback was added to PFMT, suggesting that personal devices may augment traditional PFMT<sup>41</sup>. Multiple case reports supported these findings, but more recently, a randomized controlled trial was conducted in the United States evaluating the efficacy of the PeriCoach system as a stand-alone intervention compared to supervised PFMT for the treatment of SUI and MUI<sup>4,42-45</sup>.

In this 2020 study, 54 patients aged 22-78 with either SUI or MUI were randomized to either the PeriCoach system or supervised PFMT<sup>4</sup>. Women with pelvic organ prolapse beyond the hymen, neurogenic bladder, or pure overactive bladder were excluded. At enrollment, baseline questionnaires were completed including the International Consultation on Incontinence Questionnaire Short Form (ICIQ-SF) (a quality of life measure for people with UI), the Incontinence Severity Index (ISI) (which corresponds with pad weights), the Overactive Bladder Questionnaire short form (OABq-SF), and the Female Sexual Function Index (FSFI). Baseline physical examination included a modified Oxford Score (an objective measure of pelvic floor strength) and an empty supine cough stress test. After 3 months of treatment, participants repeated these questionnaires, completed the Global Impression of Improvement of UI (PGI-I) and underwent an examination. 43 women were included in the final analysis, which met the planned sample size. Baseline characteristics and survey results were not significantly different between groups ( $p > 0.05$ ). The majority of patients were Caucasian (46%) or Hispanic (35%), premenopausal (74%), had a mean age of 46.0 years, a median parity of 2 deliveries (IQR 2,3) and a mean BMI of 31.0 kg/m<sup>2</sup><sup>4</sup>.

Home biofeedback was found to be non-inferior to PFMT for the primary outcome of change in ICIQ-SF scores (-3.95 (-3.21--6.25) vs -4.73 (-2.21--5.70)  $p=0.009$ ). This means that women using the PeriCoach system for their SUI or MUI had similar improvement in their quality of life related to urinary incontinence after 3 months compared to women undergoing standard of care supervised PFMT. UI severity by ISI scores improved in both groups and the level

of improvement was not significantly different (-1.10 vs -2.18  $p=0.15$ ). Both groups had improvement in OABq-sf scores indicated fewer overactive bladder (OAB) symptoms, however there was a greater and statistically significant improvement in the PFMT group compared to the PeriCoach system. Overall improvement as measured by the PGI-I was significantly higher in the PeriCoach group compared to PFMT (2.81 vs 2.18  $p=0.035$ ). Additionally, these users were significantly less likely to have a positive cough stress test (33% vs 23%  $p=0.013$ )<sup>4</sup>. Efficacy in treating SUI was found regardless of age or menopausal status.

FSFI scores did not significantly improve in either group, but the study was not powered to assess this outcome. Of note, both groups mean scores at baseline were in the sexual dysfunction range (25.53) and after use of the PeriCoach system, improved to a score in the normal range (27.34) with a change of 1.81 points ( $p=0.06$ ). PeriCoach users had improved pelvic muscle strength with an average increase of 1 point as measured by

the Modified Oxford Scale between baseline and follow up [3(2,3) vs 4 (3,5)  $p=0.022$ ]. Angelo et al study demonstrated that an increase from 3 to 4 on the Modified Oxford Scale indicates an average rise from 33.3 cmH<sub>2</sub>O to 50.8 cmH<sub>2</sub>O as measured by a perineometer (a 53% increase in pelvic floor strength)<sup>46</sup>. This is consistent with a prior study of the PeriCoach system, which demonstrated a 70% increase in pelvic floor strength as measured by perineometer in women completing the structured program<sup>41</sup>.

## Compliance

Compliance to use of the PeriCoach system was better than many other studies evaluating PFMT compliance with 71% (15/21) of participants adhering to the research protocol<sup>4</sup>. A prior study evaluating the effect of compliance on treatment success for UI found that regardless of compliance level, women using the PeriCoach system demonstrated an 80% or greater reduction in urine leakage in 75% of women in the study as reported by patients using

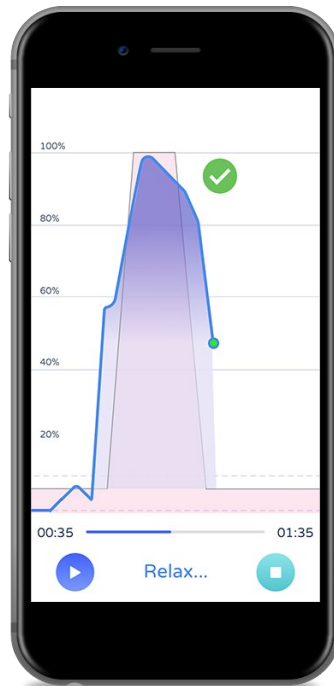


Figure 2: Contraction Trace and Technique 'Tick'

the bladder diary feature of the PeriCoach app<sup>41</sup>. Improvement in efficacy can be enhanced by active provider interaction. When providers utilize the Clinician connection feature, pelvic floor muscle strength improved significantly ( $p=0.0047$ )<sup>41</sup>.

*Use of the PeriCoach system significantly improves the quality of life with women with SUI and MUI and is non-inferior to the current standard of care*

## Patient Acceptability and Safety

Patients report high satisfaction using the PeriCoach system (Smartphone app and vaginal device). All study participants in the 2020 trial (even into their 7<sup>th</sup> and 8<sup>th</sup> decade) were able to install the PeriCoach App on their Smartphone and use Bluetooth to connect to the vaginal sensor<sup>4</sup>. Smartphone use is widespread in much of the world. As of 2019, an estimated 72% of Australians and 81% of Americans use smartphones with over 90% utilization in those under the age of 50<sup>47,48</sup>. PeriCoach users report that they appreciated being able to use the device when they lived far from physical therapy, the flexibility in timing of exercise, privacy, fun interface, no co-pay cost, and the ability to see improvement in muscle strength over time<sup>4</sup>.

The PeriCoach Sensor is coated in medical grade silicone and is well tolerated by users. In a 3 month trial only one woman out of 27 reported an adverse event (a yeast infection with concurrent intermenstrual vaginal spotting)<sup>4</sup>. In the same study the comparator PFMT group had four adverse events: bacterial vaginosis, two urinary tract infections, and one report of abnormal vaginal discharge<sup>4</sup>.

## Cost Analysis

Although PFMT is the standard of care for the non-surgical treatment of SUI and less expensive than any surgical treatment, therapy can be expensive<sup>2,31,36</sup>. The 2020 randomized controlled trial also analyzed the distance traveled and cost to patients attending PFMT in a small city with a large rural catchment area in the United States compared to women using the PeriCoach system at home. Unpublished data from this study was shared for this analysis and presented in USD. (Table 1)

## Insured Patient Costs

Although not all participants were required to pay a copayment (copay) for PFMT by their insurer, 66% of participants reported paying one. If required, women paid an average of \$59.29 per session or \$274 in copays alone for the initial evaluation with a provider (\$38) and 4 PFMT sessions (\$59 per session). If we include women who did not have a copay, the average PFMT copay was \$38, which gives a conservative estimate for the cost of evaluation and therapy at \$190.

Table 1: Distance Travelled and Cost to Patients

Zip	Insurance	Reported Cost per PT visit	Women with PT copay	Distance between clinic and home (km)
87740	Private	\$80.00	\$80.00	358.19
87112	BCBS	\$3.00		0.00
87121	Medicaid	\$50.00	\$50.00	34.93
87111	Molina/HIS	\$4.00		5.53
87114	Medicaid	\$35.00	\$35.00	37.62
87047	Tricare	\$30.00	\$30.00	34.46
87111	Medicaid	\$15.00	\$15.00	5.53
87111	BCBS	\$2.00		5.53
87031	BCBS	\$0.00		57.78
87120	BCBS	\$75.00	\$75.00	26.36
87121	BCBS	\$25.00	\$25.00	34.93
87110	BCBS	\$2.00		6.74
87123	Cigna	\$60.00	\$60.00	8.21
87144	BCBS	\$150.00	\$150.00	49.84
87008	BCBS	\$0.00		23.01
87123	BCBS	\$40.00	\$40.00	8.21
87102	Medicaid	\$10.00	\$10.00	17.63
87144	BCBS	\$40.00	\$40.00	49.84
87122	Medicare	\$4.00		9.67
87106	BCBS	\$0.00		15.14
87105	Self Pay	\$120.00	\$120.00	25.92
87107	Medicare	\$100.00	\$100.00	19.60
	<b>Averages:</b>	<b>\$38.41</b>	<b>\$59.29</b>	<b>37.94</b>

Unfortunately, the patient copay is only the tip of the iceberg when considering cost. Additionally, women drove an average of 72 minutes and traveled an average of 76 kilometers (47 miles) roundtrip to attend each supervised PFMT or clinic appointment. For women who were required to leave work for PFMT, an average of 13.2 hours of work were lost to attend the 4 sessions. A 2015 study by Ray et al. found that the average American traveling a similar amount of time to a clinic visit experienced an opportunity loss of \$43 per visit<sup>49</sup>. This would mean that each woman with UI would lose \$215 in opportunity costs for the treatment of SUI, making the total cost \$489 for each patient treated. If more PFMT sessions are required, the cost goes up accordingly. Figure 3 demonstrates the cost savings of using a PeriCoach system (\$299) compared to the increasing costs of PFMT depending on number of therapy sessions. Many women require more than 4 PFMT sessions for initial treatment or for follow up if SUI recurs in the months or years following treatment as the treatment effect wanes. Due to this reality, the true cost difference between a one-time purchase of the PeriCoach system and the need for long-term maintenance PFMT for this chronic condition becomes larger and larger over time.

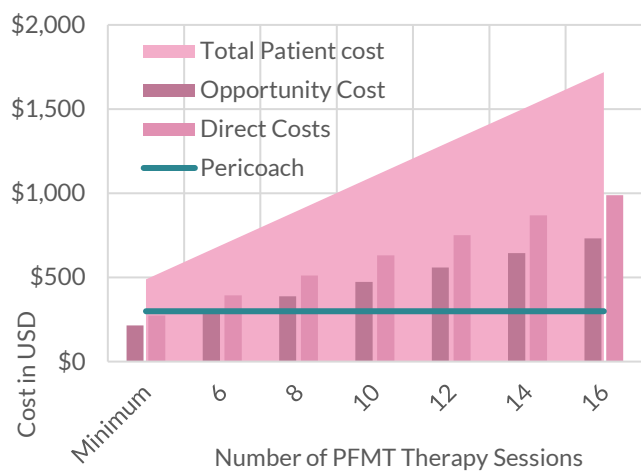


Figure 3: Costs to Patient by Number of PFMT Sessions

### Third Party Payer and Uninsured Patient Costs

The cost of PFMT can be significant for third party payers, such as private insurance companies and government coverage plans. Based on the 2020 Medicare Physician Fee schedule (Appendix – CMA Codes 2020), the base cost for 4 PFMT visits is \$268 if no biofeedback therapy is offered and is \$596 if 15 minutes of biofeedback are administered each session. Unfortunately, 4 visits is often the minimum required for the treatment of SUI. Experts suggest up to 26 therapy sessions depending on the severity of disease and

practice pattern<sup>50,51</sup>. Figure 4 demonstrates the cost of PFMT for payers as the number of therapy visits increases compared to the one-time cost of a PeriCoach Biofeedback device (\$299). Even at the minimum number of therapy sessions (4), PeriCoach demonstrates a cost benefit if biofeedback is used. This model does not include the additional cost of the initial visit with a provider to diagnose the condition of SUI and refer to a physiotherapist. This can range from \$23.46 for a 15 minute outpatient established office visit to \$229.89 for a level 5 office consultation with a specialist. Based on these estimates, the cost for evaluation and minimum treatment can be \$826 per patient with each additional PFMT visit adding an additional \$60-82 (based on Medicare reimbursement rates). Private insurers and uninsured patient typically pay a higher rate in the United States and a recent cost analysis estimated that the cost of PFMT is approximately \$1214 per patient<sup>31</sup>.

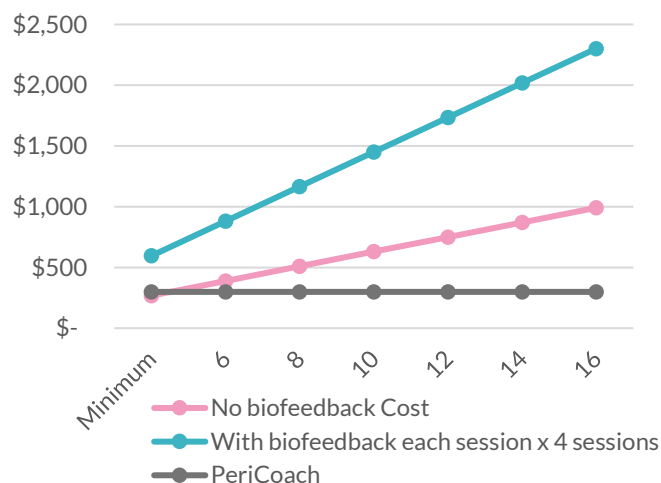


Figure 4: Cost to Payers per Non-Surgical Patient. Visits vs USD

### Price of Surgery

Although effective surgical treatments for SUI and MUI are widely available, they are much more expensive than PFMT<sup>3,31</sup>. A recent study estimates the cost of surgical therapy (Midurethral sling, Pubovaginal sling, and Burch Colposuspension variants) to range between \$5,816 and \$7961<sup>50</sup>. Refer Figure 5. Women who undergo PFMT rarely have a surgery for incontinence in the following 2 years with estimates ranging between 9.3-16%<sup>50,51</sup>. The

*The system costs significantly less to both patients and payers for similar treatment success and may prevent or delay women from needing expensive surgical treatments*

most recent Cochrane review indicates that 74% of women undergoing PFMT achieve a cure or improvement, and most women are satisfied with their treatment<sup>21</sup>. As home use of the PeriCoach system is non-inferior to PFMT, we anticipate that similar rates of success will be achieved, and these women would be unlikely to need surgery. By allowing more women to avoid the risks of surgery, complications of vaginally inserted mesh, and the cost of intervention, the PeriCoach system could provide significant savings while improving the quality of life and productivity for millions of women.

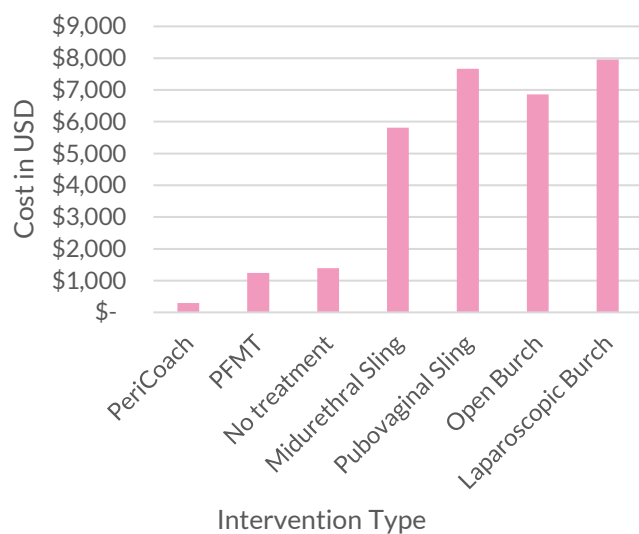


Figure 5: Cost Per Patient by Treatment Type<sup>31</sup>

## Future Directions

The PeriCoach system is effective for the treatment of SUI and MUI, but other pelvic floor conditions may improve with use as well.

### Pelvic Organ Prolapse

PFMT has also been used for the treatment of pelvic organ prolapse (POP) and shown efficacy in improving prolapse symptoms and decreasing vaginal prolapse on exam<sup>52,53</sup>. Early case reports suggest that use of the PeriCoach may improve POP symptoms based on the Pelvic Floor Distress Inventory and Pelvic Floor Impact Questionnaire after 8 weeks of treatment<sup>44,45</sup>. Although more studies are indicated to investigate the efficacy of the PeriCoach system for the treatment of POP, there is evidence that the device strengthens the muscles of the pelvic floor, which has been associated with improvement in symptoms of POP<sup>4,52,53</sup>.

*Women with UI who are unwilling to present for care, live a long distance from a physiotherapist or want to use the PeriCoach system as an adjunct to formal PFMT would benefit from using the PeriCoach system*

### Sexual Function

Evidence suggests possible improvement in sexual function with use of PeriCoach as well. UI negatively impacts women's sexual function and quality of life<sup>7,17</sup>. In one RCT of women with UI, baseline FSFI scores were <26, indicating sexual dysfunction and after a 3 month intervention with PeriCoach alone, mean scores increased into the range of normal sexual function<sup>4</sup>. When used in conjunction with formal PFMT, another study demonstrated improvement in mean scores for sexual function on the PISQ-IR compared to PFMT alone (1.71 vs -2.46, p=0.0061)<sup>54</sup>.

### Anal Incontinence

Although not studied extensively yet for the indication of anal incontinence (AI), biofeedback is commonly used as treatment and the PeriCoach system may be effective in improving continence. One case report demonstrated the PeriCoach system in conjunction with PFMT may be effective in improving bowel control by strengthening the overall pelvic floor<sup>55</sup>.

### Postpartum Pelvic Floor Reconditioning

After the birth of a child, women experience a high rate of pelvic floor disorders including UI, AI, POP, and sexual dysfunction due to the unique stresses of carrying a pregnancy<sup>56</sup>. SUI occurs in up to 30% of women in the postpartum period and without treatment 70% of these women will continue to be incontinent at 1 year postpartum<sup>13,14</sup>. Thankfully, PFMT is highly effective in treating postpartum SUI and women are highly motivated to engage in pelvic floor rehabilitation<sup>57,58</sup>. In France, all women have 20 free PFMT therapy sessions as part of the standard of care for postpartum women<sup>59</sup>. Finding time to attend PFMT can be extremely difficult due to time constraints and childcare obligations in the postpartum setting<sup>37,57</sup>. The PeriCoach system would likely be a highly effective option for the treatment of SUI in postpartum women and would cost significantly less than supervised PFMT<sup>4</sup>.

## Conclusion

Many women who struggle with SUI would like to avoid surgery due to desire for future pregnancies, health concerns precluding surgery, or preference for non-surgical management for this condition<sup>25,26</sup>. Women with UI who are unwilling to present for care, live a long distance from a physiotherapist or want to use the PeriCoach system as an adjunct to formal PFMT would benefit from using the PeriCoach system. To our knowledge, the PeriCoach system is currently the only home therapy for pelvic conditioning that has been shown to be effective for the treatment of SUI and MUI in a rigorous randomized controlled clinical trial. Use of the PeriCoach system significantly improves the quality of life with women with SUI and MUI and is non-inferior to the current standard of care. The system costs significantly less to both patients and payers for similar treatment success and may prevent or delay women from needing expensive surgical treatments.

## Appendix – CMA Codes

### PFMT Codes 2020 <sup>60</sup>

Code	Clinician Cost for Clinical setting	Meaning
90912	\$ 81.92	First 15 min of Biofeedback
90913	\$ 33.20	Additional 15 minute increments of biofeedback
97161	\$ 87.70	New visit low complexity
97162	\$ 87.70	New visit moderate complexity
97163	\$ 87.70	New visit high complexity
97164	\$ 60.27	PT Re-evaluation (follow up visits)

### Clinic Codes 2020 <sup>60</sup>

Code	Description	wRVU	National non-facility payment
99201	Office/outpatient visit, new, level 1	0.48	\$46.56
99202	Office/outpatient visit, new, level 2	0.93	\$77.23
99203	Office/outpatient visit, new, level 3	1.42	\$109.35
99204	Office/outpatient visit, new, level 4	2.43	\$167.09
99205	Office/outpatient visit, new, level 5	3.17	\$211.12
99211	Office/outpatient visit, established, level 1 (5 Min)	0.18	\$23.46
99212	Office/outpatient visit, established, level 2 (10 min)	0.48	\$46.19
99213	Office/outpatient visit, established, level 3 (15 Min)	0.97	\$76.15
99214	Office/outpatient visit, established, level 4	1.5	\$110.43
99215	Office/outpatient visit, established, level 5	2.11	\$148.33
99241	Office consult – Level 1	0.64	\$48.72
99242	Office consult – Level 2	1.34	\$92.03
99243	Office consult – Level 3	1.88	\$125.95
99244	Office consult – Level 4	3.02	\$188.75
99245	Office consult – Level 5	3.77	\$229.89

## About the Author

Dr. de Winter (formerly Barnes) is an Obstetrician Gynecologist with subspecialty training in Female Pelvic Medicine and Reconstructive Surgery. She received her medical degree at Baylor College of Medicine, completed her residency at Harvard’s Brigham and Women Hospital/Massachusetts General Hospital combined program, and fellowship at the University of New Mexico. She has a special interest in the treatment of stress urinary incontinence and has focused her research on the subject.



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