Medicare Coverage Policy ~ Decisions

Pelvic Floor Electrical Stimulation for Treatment of Urinary Incontinence (#CAG-00021N)

Exclusion Tables

Table 1a. Exclusion articles– methodologic features

Study/year	Patient characteristics	Study Design	Treatment	Dropouts	Outcome Measures	Possible threats to validity
Bent et al. 1993	45 patients with stress incontinence (14) with detrusor instability (10), or mixed (21). Age range 25-80 years	Case series	Patients had self-administered therapy for 15 minutes, separated by at least 4 hrs, twice a day for 6 weeks. 20Hz applied for detrusor instability, 50Hz for stress incontinence.		Leakage episodes Pad use Pad test Standing stress test Standing CMG Resting/dynamic urethral closure pressure profiles Questionnaire	Potential for selection bias Exclusion criteria included "poor medical health" without further specification
Bratt, et al 1998	48 women with unstable detrusor and urge incontinence originally enrolled in a short-term study in 1989. 30 women located/surveyed Mean age of respondents 62 years (age range of original 48 women 15-79 years)	Questionnaire	Patients received 5-10Hz for 20 minutes, twice a week, at least five times	18/48 surveyed 10 deceased 2 disabled secondary to stroke, 5 lost to follow-up, 1 counted twice in the original study	6 close-ended questions including: Do you have any leakage of urine? If you have leakage, how often does it happen? IF you do have leakage, what is the worse problem? Were you satisfied with the electrostimulation as a treatment method? Would you recommend the treatment to a good friend?	Potential for selection bias, performance bias. Authors quote 90% response rate, however, 18 people could not be surveyed of the original 48. Lack of rigor of survey instrument.
Caputo, et al	76 women- 19 patients with	Case series	Patients received electrical stimulation for 15 minutes at 20 Hz		Urinary incontinent episodes	Potential for selection bias

al 1993	19 patients with SI, 30 patients with DI, 27 with mixed. Average age: 52.6 years		minutes at 20 Hz, once a week for 6 weeks. Patients were taught Kegel exercises and asked to perform exercise 50 times daily.		episodes Voiding frequency (Measured by bladder diary)	selection bias Numerous confounders

Table 1a. Exclusion articles– methodologic features (cont'd)

Study/year	Patient characteristics	Study Design	Treatment	Dropouts	Outcome Measures	Possible threats to validity
Dumoulin, et al 1995	8 female patients (out of 10 volunteers) with GSI, persisting more than 3 months after delivery Average age 32 years	Case series	Subjects received nine treatment sessions over 3 weeks, consisting of two 15-minute sessions of neuromuscular electrical stimulation, followed by a 15 minute pelvic floor muscle exercise program (50 Hz applied)		Maximum muscle contractions (pressure using perineometry) Urine loss (pad test) Frequency of incontinence (self diary)	Small sample size (n=8) and short follow-up time (3 weeks) Confounders include that patients received both electrical stimulation and an exercise program, and therefore it is unclear what benefit can be attributed to which element of therapy.
Eriksen, et al 1989	55 women with urinary stress incontinence awaiting surgical repair Average age 49 years	Case series	Chronic stimulation (25 Hz) applied anally or vaginally for a median of 5.4 months (Range 0.5 - 29 months). Pts instructed to use stimulator regularly and as much as possible every day for at least 3 months before effect was evaluated. If improved, they were encouraged to continue therapy. If no effect, colposuspension urethropexy was recommended.		Urethral closing pressure Amount of leakage	Potential for selection bias Potential for attrition bias- little data provided about the use of electrical stimulation No standardization of protocol. Large range of treatment time – 15 days to 29 months. Outcome measures were used that are not typically reported
Fossberg et al 1990	91 patients (11 males and 80 females) with unstable detrusor,	Case series	Patients received 12 treatments of 5-10 Hz for 20 minutes	17 dropouts 15 females	Frequency/volume charts Cystometry	Potential for selection and attrition bias

	detrusor, frequency and urge incontinence Mean age 53 years (20-78 years)		minutes	females 2 males	Cystometry Flowmetry Subjective assessment	
Kralj, B 1999	111 women with moderate SI	Case series	Patients received electrical stimulation 20 Hz for 1.5-2 hours daily for 3 months		Pad test [Outcomes assessed six months after beginning of treatment; 3 months after terminating treatment.]	Potential for selection bias. Little data provided on patient characteristics, as well as inclusion/exclusion criteria.
Miller et al 1998	31 women with GSI Average age: early 50's	Case series	15 patients treated daily 16 treated every other day Used device for 15 minutes twice a day or every other day for 20 weeks [50Hz]	3/31	Modified pad test QOL questionnaire Total number of incontinent episodes/ 3 day period as recorded in voiding diary	Potential for selection bias and performance bias.
Study/year	**Patient characteristics**	**Study Design**	**Treatment**	**Dropouts**	**Outcome Measures**	**Possible threats to validity**
Richardson, et al 1996	31 women with GSI Average age 50 years Average years incontinent 6.5	Case series	Study conducted at 6 sites. Patients were assigned consecutively to either daily or every-other-day pelvic floor electrical stimulation for 15 minutes twice a day [50Hz applied]	10/31 one year follow-up	Leakage episodes over 3 days (voiding diary) Pad count Leakage amount Subjective assessment and quality of life	Potential for selection bias and performance bias.
Sand PK 1996	26 women with mixed incontinence complicated by a low-pressure urethra Average age 63.2 years Average years incontinent 8.3 (2-30)	Case series (Retrospective)	Patients used device twice a day [20 Hz] for 15 minutes for 8 weeks None of the women received concomitant care for incontinence	5/26	Visual analogue symptom scales Weekly incontinent epsidoes	Potential for selection bias. Nearly 25% dropout.

Siegel, et al 1997	72 patients at 8 study sites. 66 completed 20 week protocol. 36 patients with urge, 30 with stress. Average age 53 years (34-82) Average years incontinent 9.7-10.3	Case series	33 patients treated daily, and 35 patients treated every-other-day with either 12.5 Hz or 50Hz for 15 minutes twice a day Subjects agreed to no other incontinence treatments during duration of study	4/72	Leakage episodes, nocturnal episodes, voiding frequency, total voids, pad count Patient subjective assessment and quality of life	Potential for selection bias Broad exclusion criteria
Zollner-Nielsen, et al 1992	38 female patients with frequency, urgency, or urge incontinence Median age 71 years (35-90) 74% of patients were 60 years or older	Case series	Patients treated for 20 minutes, twice a week Received 5-15 treatments	7/38	Mean bladder volume Number of micturitions Questionnaire	Potential for selection bias Potential for performance bias

Table 1b. Exclusion articles– outcomes

Study/year	**Pt recorded diaries** **% % pts** **Measure Pre- Post- change[1] improv[2] %cure[3]**	**Pad test (grams)** **% % pts %** **Pre- Post- change[1] improv[2] cure[3]**	**Comments**
Bent et al 1993	Not reported However, authors state that incontinent episodes decreased in 6 patients with SI, 1 patient with DI, 6 patients with mixed. p=NS	Not reported However, authors state that pad test results improved for 8 patients with SI and 5 patients with DI. p=NS	Objective criteria defined by authors did not show any improvement after treatment. Subjective measures, based on a questionnaire, did demonstrate success but it is unclear as to the significance and reproducibility of survey results. Authors state that results were statistically significant but do not provide specific data. Short study period – 6 weeks
Bratt et al, 1998	Not measured 21 women (78%) reported symptoms of urge incontinence, 13 women having symptoms daily. 19 women (70%) reported symptoms of stress incontinence. 21 women would recommend maximal	Not measured	Limited conclusions can be made since data is subjective. No objective data reported. Of note, a large number of women were suffering from stress incontinence that ten years earlier were treated for urge. The prevalence of urge incontinence was

	21 women would recommend maximal stimulation to a friend.		urge incontinence was reported to be higher in the follow-up than the original study.
Caputo, et al 1993	Not reported Overall objective improvement 76% ; 89% for GSI, 73% for DI, 70% for mixed. [objective improvement defined as a reduction in urinary incontinence episodes by 50%, or reduction in voiding frequency by 50%, or to 10 or fewer voids per 24 hours.]	Not measured	No statistical analyses provided. Stimulation applied once a week – appears to be a departure from practice in most other studies. Study lasted 6 weeks. Achieved up to one-year follow-up in only 40% of patients [avg 6.4 months]. The fact that only 15% relapsed is difficult to interpret due to attrition bias. Of note, authors state that controlled clinical trials are needed to determine its efficacy and standardize stimulation protocols before its widespread use.
Dumoulin, et al 1995	Leaks/week 16.3 4.0 75% NR NR	74.4 24.4 67% NR NR p= 0.012	Authors provide little raw data for results to be reassessed. Broad exclusion criteria, including patients with diabetes and heart disease. Authors do note that "further studies are needed to validate this…protocol."

Table 1b. Exclusion articles– outcomes (cont'd)

Study/year	**Pt recorded diaries** **% % pts %** **Measure Pre- Post- change[1] improv[2] cure[3]**	**Pad test (grams)** **% % pts %** **Pre- Post- change[1] improv[2] cure[3]**	**Comments**
Eriksen et al 1989	Not measured Authors state that 68% of patients were continent or had improved. (Cure defined as positive urethral closure pressure found, and no leakage observed during the stress provocation tests) At 2 year follow-up, success rate was reduced to 56%.	Not measured	Data analysis minimal. Authors only provide data at 2 year follow-up, although outcome measures were apparently obtained at 3 months. Data is not provided on all 55 women initially enrolled. Authors do not define

			Authors do not define "improved"
Fossberg, et al 1990	Leaks/day at 6 weeks 1. 8.0 12 % NR NR p=0.003 Leaks/night at 6 weeks 1.6 1.1 31% NR NR	Not measured	Study conducted in Norway with a device that is only slightly analogous to that used in the US Short study time Are reductions in micturition clinically significant? At 6 weeks post treatment, almost half of patients felt their condition was unchanged.
Kralj, B 1999	Not measured Authors state that 50.5 % of patients were cured, 23.4% improved, 26.1% failed. [Cure defined as no subjective complaints and pad tests were negative; improved defined as no subjective complaints, and pad test not negative]	Not reported	No statistical analysis provided. Authors conclude by stating that "the efficacy of treatment depends on the patient selection, parameters of electrical stimulation, stimulator of the pelvic floor muscles, mode of stimulation and on motivation of the patient." Authors, however, provide no such guidance. Definitions of cure and improvement are not standard.
Miller et al 1998	Leaks/3day at 20 weeks Responders (n=19) 7.6 1.71 78 % NR NR Nonresponders (n=9) 7.8 9.51 - 22% NR NR	Not reported	Study designed to have adequate power to detect a reduction of 2.1 leakage episodes over 3 days. Is this clinically significant? Data presentation unusual. There were two groups, yet no data was presented for those two separate groups. Instead, data stratified by those patients who showed response [defined as 50% decrease in total number of leakage episodes] vs those who did not respond. P values not reported.
Study/year	**Pt recorded diaries** **% % pts %** **Measure Pre- Post- change[1] improv[2] cure[3]**	**Pad test (grams)** **% % pts %** **Pre- Post- change[1] improv[2] cure[3]**	**Comments**
Richardson, et al 1996	Leaks/3 day at 20 weeks Daily (n=13) 8.6 5.6 35% 30% 23%	Daily (n=13) 48.7 36.7 25% NR	Since there is no direct comparison between this therapy and conventional therapy, it is difficult to discern that similar results would have not been

	8.6 5.6 35% 39% 23% p=0.06 Every-other-day (n=15) 6.9 3.0 56% 20% 53% p=0.04 Leaks/3 day at one year Users (n=10) 9.2 2.0 78% NR NR p=0.009 Nonusers (n=11) 5.8 4.6 21% NR NR p=0.06	48.7 36.7 25% NR NR p=0.11 Every-other-day (n=15) 12.5 6.9 45% NR NR p=0.38	would have not been reported for Kegel/biofeedback. Short study time (20 weeks) Cure improvement rates were not statistically significant. Only total leakage episodes for daily users was statistically significant. Little data is provided on one-year follow-up. At one year, ½ of users were performing Kegel and some started bladder training programs, causing confounders.
Sand PK 1996	Not measured	Not measured	Although there was subjective improvement in voiding frequency, urgency and stress incontinence, there is question of clinical significance. For example, between therapy, pts had 1.5 hrs between voids. After therapy, time between voids was 2.08 hrs. Is 30 minutes clinically significant? The actual number of incontinent episodes showed no difference between pre and post treatment. Authors do not define cure/improvement.
Siegel, et al 1997	Leaks/3day Urge (n=35) 9.6 5.3 45% NR NR p<0.001 Mixed (n=33) 9.6 3.9 59% NR NR p<0.001	Not measured	Authors state that there was no difference in data between daily and every-other-day treatment, although actual numbers are not provided. Short study time – 20 weeks. Logistic regression demonstrated lack of response associated with number of previous therapies.

Study/year	Pt recorded diaries % % pts % Measure Pre- Post- change[1] improv[2] cure[3]	Pad test (grams) % % pts % Pre- Post- change[1] improv[2] cure[3]	Comments
Zollner-Nielsen, 1992	Leaks/48 hrs 7.4 5.9 20% NR NR p<0.01	Not measured	Incomplete data provided. Authors combine cured/improved with no p values. Study included 8 patients with neurologic causes of UI. No explanation of dropouts. No description of instrument used to assess subjective opinions. Results were similar for patients < 60 years and > 60 years.

[1] % change – Defined as the percent decrease in the frequency of incontinence over a specified time period, calculated by the following equation:

pretreatment episodes/period - posttreatment episodes/period X 100

pretreatment episodes/period

[2] % pts improv – Defined as the percentage of patients with 50% or greater decrease in the frequency of incontinence, as calculated by the previous equation.

[3] % cure – Defined as the percentage of patients with 100% decrease in frequency of incontinence, i.e., no incontinent episodes over the specified time period.

[4] % change – Defined as the percent decrease in the amount of urine lost in grams, following provocative maneuvers, calculated by the following equation:

pretreatment pad weight difference - posttreatment pad weight difference x 100

pretreatment pad weight difference

[5] % pts improv – Defined as the percentage of patients with 50% or greater decrease in the amount of urine lost in grams following provocative maneuvers.

[6] % cure – Defined as the percentage of patients with 100% decrease urine loss, ie no urine lost following the provocative maneuvers.

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Key to Tables

ICS International Continence Society

MI Mixed incontinence (stress and urge incontinence)

%change Percent change in incontinence (frequency by pt recorded diary or urine loss on pad test)

%cure Percent of patients with no further incontinence

% pts improv Percent of patients with >50% decrease in incontinence (frequency by pt recorded diary or urine loss on pad test)

PFES Pelvic floor electrical stimulation

PME Pelvic floor muscle exercise

SI Stress incontinence

UI Urge incontinence

Selection bias Imbalances in patient characteristics between groups with potential for differences to affect outcomes

Performance bias Inequality in the intensity of treatment given between groups

Attrition bias Significant number of dropouts in one or more study arms, not taken into account in the statistical analysis