

Incontinence Therapy

Selected Treatments and Devices

Medical Policy



When services are covered

We cover the following treatments for **urinary incontinence**:¹

- **Behavioral training** such as bladder training, prompted voiding, pelvic muscle exercise training⁸
- **Medications** to treat incontinence
- **Collagen implantation**, when all of the following are met:
 - one of the following indications:
 - stress urinary incontinence caused by intrinsic sphincter weakness^{3,5,26}
 - post-traumatic or post-surgical injury^{4,5}
 - urethral hypermobility in females with abdominal leak point⁵ less than 100 cm H₂O⁴
 - up to five injections are covered, since beyond that, the patient would be considered a treatment failure.³
- **Sacral nerve stimulator (sacral nerve neuromodulation) trial and surgical implantation** for patients who have failed or could not tolerate conservative treatments and when one of the following are met:⁷ (see electrical or magnetic pelvic floor stimulation below)
 - the patient has **disabling urge incontinence** (not stress incontinence)²⁵
 - the patient has **non-obstructive urinary retention** and symptoms of **urgency or frequency** not due to a neurologic condition.^{9,13,25}

For medically necessary diagnoses, see footnote 25.

- **Non-implantable pelvic floor electrical stimulation** in accordance with CMS guidelines for **Medicare HMO Blue and Medicare PPO Blue members**, for the treatment of **stress and/or urge urinary incontinence** in cognitively intact patients who have failed a trial of pelvic muscle exercise training.¹⁶
- **Surgery**.^{1,2}

When services are not covered

We do not cover the following services. While some people may believe in the value of these approaches, they have not been proven to the highest statistical standards¹ to improve incontinence in patients:

- **Computerized or electrical biofeedback**, since there is no evidence that this method of biofeedback is more effective than simple verbal "biofeedback" with pelvic muscle exercises.^{1,6,11,12,15,19} However, for our **Medicare HMO Blue and Medicare PPO Blue** patients, we must provide the same coverage as does Medicare, so this service is covered for these patients only.⁴
- **Vaginal weight training** with specially designed weights (cones)¹
- **Pelvic floor electrical or magnetic stimulation (PFES)**^{1,10,14,18,21,22,28}
- **Teflon[®] injections (periurethral)**^{3,26}
- **Autologous fat and autologous ear chondrocytes as periurethral bulking agents**²⁶
Effective 5/05.

- **Collagen injections** for patients whose incontinence is due to hypermobility or detrusor instability, since this procedure will not address these problems (see American Medical Association statement below⁵).
- **Transanal radiofrequency treatment of fecal incontinence**²⁰ **Effective 1/05.**
- **Biofeedback as a treatment of fecal incontinence** because there is no evidence that biofeedback training adds benefit to conventional treatment in the management of constipation. The evidence for biofeedback based on observational studies and methodologically weak controlled trials can only be viewed as tentative.^{23, 24} **Effective July 2004.**
- **Sacral nerve stimulation (sacral nerve neuromodulation)** for the treatment of fecal incontinence, chronic constipation, or chronic pelvic pain.²⁵
- **Other applications of sacral nerve stimulation (sacral nerve neuromodulation)**, including but not limited to treatment of stress incontinence or urge incontinence due to a neurologic condition (e.g., detrusor hyperreflexia, multiple sclerosis, or spinal cord injury), other types of chronic voiding dysfunction.²⁵
- **Periureteral bulking agents as a treatment of vesicoureteral reflux**²⁷ **Effective 2/06.**

Individual consideration

All our medical policies are written for the majority of people with a given condition. Each policy is based on medical science. For many of our medical policies, each individual's unique circumstances may be considered in light of current scientific literature. For consideration of an individual patient, physicians may send relevant clinical information to:

For services already billed:	Prior to performance of service:
BCBSMA, Provider Services P.O. Box 5000 Rockland, MA 02370	BCBSMA, Appeals Unit One Enterprise Drive Quincy, MA 02171 Tel: 1-800-327-6716 Fax: 1-888-641-5330

Managed care guidelines

- Any specialist visit requires a referral for Medicare HMO Blue.
- For all other Managed Care plans, any specialist visit requires a referral, except for visits performed by OB/GYN specialists.
- Authorizations are required for hospital admissions.
- Authorizations are not required.

Indemnity and PPO Guidelines

All authorization requirements are determined by the individual's subscriber certificate, however:

- Authorizations are required for all inpatient services
- Authorizations are not required for most outpatient services as determined by the individual's subscriber certificate
- Referrals to a specialist are not required.

Billing information

Procedure codes are from current CPT, HCPCS Level II, Revenue Code, and/or ICD-9-CM manuals, as recommended by the American Medical Association, Centers for Medicare and

Medicaid Services and American Hospital Associations. Blue Cross Blue Shield Association national codes may be developed when appropriate.

The following codes may be used for sacral nerve stimulator surgical implantation for urinary incontinence **only** when the patient has **disabling** urge incontinence or urinary retention and symptoms of urgency or frequency, and all of the coverage criteria stated on this policy is met.

For Sacral Nerve Stimulation:

- Bill CPT code 64561 for percutaneous implantation of neurostimulator electrodes; sacral nerve
- Bill CPT code 64581 for incision for implantation of neurostimulator electrodes; sacral nerve
- Bill CPT code 64585 for revision or removal of peripheral neurostimulator electrodes.
- Bill CPT code 64590 for insertion and replacement of peripheral neurostimulator pulse generator or receiver, direct or inductive coupling.
- Bill CPT code 64595 for revision or removal of peripheral neurostimulator pulse generator or receiver.
- Bill HCPCS Level II code A4290 for sacral nerve stimulator test lead, each.

The above services will deny, with no patient balance, if submitted with a diagnosis other than the listed covered indications.

- Bill CPT code 95970 for electronic analysis of implanted neurostimulator pulse generator system (e.g., rate, pulse amplitude and duration, configuration of wave form, battery status, electrode selectability, output modulation, cycling, impedance and patient compliance measurements); simple or complex brain, spinal cord, or peripheral (i.e., cranial nerve, peripheral nerve, autonomic nerve, neuromuscular) neurostimulator pulse generator/transmitter, without reprogramming.
- Bill CPT code 95971 for electronic analysis of implanted neurostimulator pulse generator system (e.g., rate, pulse amplitude and duration, configuration of wave form, battery status, electrode selectability, output modulation, cycling, impedance and patient compliance measurements); simple spinal cord, or peripheral (i.e., peripheral nerve, autonomic nerve, neuromuscular) neurostimulator pulse generator/transmitter, with intraoperative or subsequent programming.
- Bill CPT code 95972 for electronic analysis of implanted neurostimulator pulse generator system (e.g., rate, pulse amplitude and duration, configuration of wave form, battery status, electrode selectability, output modulation, cycling, impedance and patient compliance measurements); complex spinal cord, or peripheral (except cranial nerve) neurostimulator pulse generator/transmitter, with intraoperative or subsequent programming, first hour.
- Bill CPT code 95973 for electronic analysis of implanted neurostimulator pulse generator system (e.g., rate, pulse amplitude and duration, configuration of wave form, battery status, electrode selectability, output modulation, cycling, impedance and patient compliance measurements); complex spinal cord, or peripheral (except cranial nerve) neurostimulator pulse generator/transmitter, with intraoperative or subsequent programming, each additional 30 minutes after first hour (List separately in addition to code for primary procedure)
- Bill HCPCS Level II code E0752 for implantable neurostimulator electrode, each.
- Bill HCPCS Level II code E0756 for implantable neurostimulator pulse generator.

Non-implantable Electrical Stimulators

- Bill CPT code 97014 for Application of a modality to one or more areas; electrical stimulation, unattended.

For Collagen Implantation:

- Bill CPT code 51715 for endoscopic injection of implant material into the submucosal tissues of the urethra and/or bladder neck.

- Bill HCPCS Level II code Q3031 to report collagen skin test.
- Bill HCPCS Level II code L8603 for injectable bulking agent, collagen implant, urinary tract. 2.5 ml. syringe, includes shipping and necessary supplies.
- Bill HCPCS Level II code L8606 for injectable bulking agent, synthetic implant, urinary tract. 1 ml. syringe, includes shipping and necessary supplies.

The above services will deny, with no patient balance, if submitted with a diagnosis other than the listed covered indications.

For DME Providers Only:

- Bill HCPCS Level II code A4290 modifier NU (purchase), for sacral nerve stimulation test lead, each.

Hospital Billing Outpatient for collagen implantation:

- Bill CPT code 51715 for endoscopic injection of implant material into the submucosal tissues of the urethra and/or bladder neck.
- Bill revenue code 490 (ambulatory surgical procedures)

Hospital Billing Inpatient for sacral nerve stimulator surgical implantation:

- For implantation or replacement of peripheral neurostimulator, bill ICD.9.CM procedure code 04.92

The services noted below will reject according to the Medical Technology Assessment guidelines **(covered for Medicare HMO Blue and Medicare PPO Blue only)**, leaving no patient balance.

Biofeedback: For Physicians

- Bill CPT code 90901, for biofeedback training by any modality
- Bill CPT code 90911, for biofeedback training, perineal muscles, anorectal or urethral sphincter, including EMG and/or manometry

Biofeedback: For Hospitals

- Bill revenue code 917, and the appropriate CPT code

The following services will deny, with no patient balance, if billed, as these services do not meet our medical technology assessment guidelines:

- Electrical pelvic floor stimulation, HCPCS Level II code E0740 **(Covered for Medicare HMO Blue and Medicare PPO Blue only)**.
- Electromyography (EMG), biofeedback, device, HCPCS Level II code E0746 **(Covered for Medicare HMO Blue and Medicare PPO Blue only)**.
- Vaginal weight training
- Teflon® injections (periurethral)
- Treatment(s) for incontinence, pulsed magnetic neuromodulation; per day, Category III CPT code 0029T **(Non covered for all Plans)**
- Computerized or electrical biofeedback, CPT code 90901 **(covered for Medicare HMO Blue and Medicare PPO Blue only⁴)**
- Biofeedback training, perineal muscles, anorectal or urethral sphincter, including EMG and/or manometry. CPT code 90911 **(covered for Medicare HMO Blue and Medicare PPO Blue only⁴)**

Other Information

- For Medical Technology Assessment Guidelines refer to document # 350.
- For the Medical Technology Assessment Non-Covered Services list refer to document # 400.

- Pessary is an item that may be billed from the physician's office. When billing for this item use the appropriate HCPCS Level II procedure code A4561 (pessary, rubber, any type) or A4562 (pessary, non-rubber, any type).

Patient Information

American Urological Association, Inc. 1120 North Charles Street , Baltimore, MD 21201	410-727-1100
Agency for Health Care Policy and Research Publications Clearinghouse, Post Office Box 8547, Silver Spring, MD 20907 Web: http://www.ahcpr.gov/guide/ <i>Ask for the free booklets called Understanding Incontinence Patient Guide and Helping People with Incontinence Caregiver Guide.</i>	800-358-9295
Alliance for Aging Research 2021 K Street, N.W., Suite 305, Washington, DC 20006 <i>Ask for information on bladder training programs.</i>	202-293-2856
Bladder Health Council c/o American Foundation for Urologic Disease 200 West Pratt Street, Suite 401, Baltimore, MD 21201	800-242-2383
National Association for Continence P.O. Box 8310, Spartanberg, SC 29305	800-BLADDER
Simon Foundation for Continence Box 835, Wilmette, IL 60091	800-23-SIMON

Definitions

Incontinence is the inability to hold urine. There are several types, such as stress-urge incontinence, detrusor instability, and others. Many women experience some incontinence after childbirth, and with increasing age. Many men experience incontinence along with prostate problems. About 13 million people in the US are affected.

biofeedback: generally, this term can mean any type of feedback about a body function, like blood pressure, heart rate, muscle strength, and other functions. Others use it to mean a computerized or electrical system to automatically give a person information about these type of bodily functions, so that a person could then modify the function.

cones (vaginal weight training): small, specially designed weights ("cones") that a woman may place in the vagina and hold there, to strengthen

conservative: less aggressive, simpler, more traditional therapy

detrusor instability: a bladder that contracts and empties out urine, even though it is not full, or when the person does not intend to urinate

electrical pelvic floor stimulation: various types of devices may be used to send electrical signals to the muscles in and around the bladder area. One type of device is placed inside the vagina, and sends electrical signals to either "exercise" the bladder muscle, or to keep the bladder from emptying at the wrong time. These devices require further research to compare them to existing standard treatments. **Magnetic pelvic floor stimulation** does not require an internal electrode; patients sit, fully clothed on a specialized chair; may be done in the doctor's office.

fecal incontinence: involuntary leakage of stool from the rectum and anal canal.

hypermobility: a weakness in the tissues around the bladder and urethra. If these tissues do not have the right support from the rest of the pelvic area, then under simple stress such as coughing or

laughing, these bladder and the urethra shift position, and urine may leak out. This is the most common cause of incontinence.

intrinsic sphincter weakness: a problem with the natural ring of muscle that holds urine, at the urethra (the tube between the bladder and the outside of the body); often due to trauma, or from having had surgery on the prostate or bladder area

periurethral collagen injection: collagen is a protein. Peri-urethral means around the **urethra**. In some patients with weakness around the bladder area, injecting collagen with a needle might strengthen the area, to make a better seal for the outside of the bladder area. The needle can be placed through the vaginal, or through the skin in the groin area. This procedure may done over the course of two to three visits.

polytetrafluoroethylene (Teflon®) is a material that can be injected into the area around the outside of the bladder area, instead of collagen, to try and strengthen the area.

overflow incontinence: when the bladder is too full, and urine spill out

sacral nerve stimulator: this is a device that is surgically implanted into the patient (different from electrical pelvic floor stimulation) to treat urge incontinence. A cut is made over the lower back area, and electrodes are positioned into the roots of the sacral nerve, which controls part of the bladder muscles. A computerized control box is placed in the lower abdomen area. Patients can use a magnet to turn the device on and off.

sphincter: the tiny natural ring of muscle that helps control urine flow

stress-urge incontinence: involuntary leakage of urine during a sudden action such as coughing, laughing, or straining; due to weakness in some of the tissues around the bladder and nearby areas

radiofrequency energy treatment: this treatment involves a tool that creates heat to create a change in the lining of the anal canal.

urethra: the natural tube connecting the bladder and the outside opening where urine flows. In men, it is inside the penis

urge incontinence: involuntary leakage of urine during a strong desire to urinate

vaginal weight training (cones): small, specially designed weights (“cones”) that a woman may place in the vagina and hold there, to strengthen the muscles in the pelvic area. Over time, increasingly heavy weights are used.

Scientific background

Issued 6/97. Coverage for periurethral collagen injections were added. Updated 12/97 to include 1998 CPT code revision (CPT 90911). No changes in coverage were made. Updated 6/98 to exclude coverage for sacral nerve stimulators for urge incontinence. Updated 1/99 to add coverage for sacral nerve stimulation for urge incontinence. Updated 6/99 to include science on behavioral training for urinary incontinence, and to add coverage for sacral nerve stimulator for treatment of urinary retention and symptoms of urgency/frequency. Updated 6/00 to include science on biofeedback and electrical floor stimulation. Reviewed 6/01, no changes in coverage were made. Updated 9/01 to include coverage for non-implantable pelvic floor electrical stimulators for treatment of stress and/or urge urinary incontinence for Blue Care 65 members. Updated 6/01 to clarify covered diagnoses for sacral nerve stimulators. Reviewed 6/02 MPG Urology, no changes in coverage were made. Reviewed 6/03 MPG Urology, no changes in coverage were made. Reviewed 6/04 MPG urology, no changes in coverage were made. Reviewed 1/05 BCBSA National Policy issued 4/04; excluded coverage of transanal radiofrequency treatment of fecal incontinence effective immediately. Reviewed 3/05 BCBSA National Policy issued 4/04, no change in non coverage of pelvic floor stimulation as a treatment of urinary incontinence; updated billing information. Reviewed 4/05 BCBSA National Policy issued 3/05, without change in non coverage of pelvic floor stimulation as a treatment of urinary incontinence, 2 additional references added. Reviewed 4/05 BCBSA Policy issued 3/05 after an updated literature review, no changes in coverage related to transanal radiofrequency treatment of fecal incontinence. Updated 4/05 to add coverage exclusion of biofeedback for the treatment of fecal incontinence (removed from #178 Complementary Medicine Policy) with rationale, billing information and references. Reviewed 4/05 BCBSA National Policy issued 3/05 with no change in coverage exclusion of biofeedback for the treatment of fecal incontinence. Reviewed 5/05 to clarify coverage exclusions of sacral nerve stimulation (sacral nerve neuromodulation) based on BCBSA National Policy issued 7/04. Reviewed 5/05 BCBSA National Policy issued 4/05 with clarification of coverage exclusion of autologous fat and autologous ear chondrocytes as periurethral bulking agents as well as with rationale, billing information and references. Reviewed 6/05 MPG-urology, no changes in coverage were made. Updated

1/06 following review of BCBSA National Policy issued 6/05 excluding coverage of periurethral bulking agents as a treatment of vesicoureteral reflux with rationale, billing information and references, effective 2/06. Reviewed 3/06 BCBSA National Policy issued 12/05 without change in coverage exclusion of transanal frequency treatment of fecal incontinence. Reviewed 3/06 BCBSA National Policy issued 12/05 without change in policy statement specific to sacral nerve stimulation. Reviewed 5/06 BCBSA national policy issued 3/06 without change in coverage exclusion of pelvic floor electrical or magnetic stimulation as a treatment of urinary incontinence, one reference added. Reviewed 6/06 MPG-Urology, no changes in coverage were made. Reviewed 9/06 BCBSA National policy issued 7/06 with no change in coverage exclusion of biofeedback for the treatment of fecal incontinence, additional references added. Reviewed 10/06 BCBSA National policy issued 7/06 to include references # 17 and 18 under footnote #25.

¹ Based upon the Agency for Health Care Policy and Research assessment by Fantl JA, Newman DK, Colling J et al. Urinary Incontinence in Adults: Acute and Chronic Management. Clinical Practice Guideline No. 2, 1996 Update. AHCPR Publication No. 96-0682 March 1996. Available on-line at <http://www.ahcpr.gov/> or by calling 1-800-358-9295, or by AHCPR Instafax at 1-301-594-2800 (Quick Reference Guide for Clinicians).

Key to the AHCPR assessment recommendations:

- A. The recommendation is supported by scientific evidence from properly designed and implemented controlled trials providing statistical results that consistently support the guideline statement.
- B. The recommendation is supported by scientific evidence from properly designed and implemented clinical series that support the guideline statement.
- C. The recommendation is supported by expert opinion.

Treatment of Urinary Incontinence The three major categories of treatment are Behavioral, Pharmacologic, and Surgical. Treatment options including their risks, benefits, and outcomes should be discussed with the patient so that informed choices can be made. As a general rule, the first choice should be the least invasive treatment with the fewest potential adverse complications that is appropriate for the patient. For many forms of UI, behavioral techniques meet these criteria. However, an informed patient's preference must be respected. A combination of surgical, behavioral, and pharmacologic interventions may be appropriate, but more research is required to determine the optimum treatment combinations for specific patient groups.

Behavioral Techniques Behavioral techniques decrease the frequency of UI in most individuals when provided by knowledgeable health care providers, have no reported side effects, and do not limit future treatment options. Behavioral therapies can be divided into (1) caregiver-dependent techniques for patients with cognitive and motor deficits and (2) those requiring active rehabilitation and education techniques. These distinctions are arbitrary, however, and any individual's ability to actively participate varies on a continuum from complete dependence to full participation in the most complex behavioral therapies. For example, physically impaired patients who are cognitively intact may benefit from bladder training, pelvic muscle exercises (PMEs), and biofeedback therapy, but may depend on caregivers for assistance to the toilet. Behavioral techniques are listed below in the order of those requiring passive involvement to those requiring active participation:

- Toileting assistance -- routine/scheduled toileting, habit training, and prompted voiding.
- Bladder retraining.
- Pelvic muscle rehabilitation -- PMEs,
- PMEs and bladder inhibition augmented by biofeedback therapy,
- PMEs augmented with vaginal weight training,
- pelvic floor electrical stimulation.

All behavioral techniques involve educating the patient, the caregiver, or both, and provide positive reinforcement for effort and progress. Behavioral techniques should be offered to motivated individuals who wish to avoid more invasive procedures or dependence on protective garments, external devices, and medications. Behavioral techniques have few reported side effects and do not limit future treatment options. Behavioral techniques can increase patient understanding of lower urinary tract function and the environmental factors affecting symptoms. These techniques can improve control of detrusor and pelvic muscle function. They generally require patient or caregiver involvement and continued practice. If motivated, most people treated with behavioral techniques show improvement ranging from complete dryness to decreased incontinence episodes. Improved bladder control can occur even in the cognitively impaired. Behavioral techniques can also be used in combination with other therapies for UI. Published results indicate that determining the precise level of effectiveness of behavioral interventions is limited by the following factors:

- Use of different outcome criteria.
- Variability in number, duration, and frequency of and adherence to treatment sessions.
- Variability of comprehensiveness in training procedures.
- Absence or variability in follow-up data.
- Concurrent application of multiple interventions that confound outcomes.
- Unspecified criteria for group assignment.
- Use of heterogeneous samples.
- Lack of measurement of independent variables.
- Uncontrolled inclusion of patients who had failed previous incontinence treatments.
- Lack of standardized terminology for the various behavioral techniques.

Because of the lack of standardized terminology, the reader must examine each study carefully and be alert to differences even in studies that appear to use the same terms. In general, however, studies show that behavioral interventions are effective in reducing incontinence. The cost of behavioral treatments compared with other treatments has not been studied, but two reports showed that the behavioral techniques enabled a considerable number of patients to avoid or postpone surgery.

Assessment Before Behavioral Intervention Before implementing behavioral therapy, patients should undergo the basic evaluation. Behavioral approaches must be tailored to the patient's underlying problem, such as bladder training or habit training for urge UI and pelvic muscle rehabilitation for SUI. Patients with overflow UI are not primary candidates for behavioral intervention.

Toileting assistance Toileting assistance interventions include routine or scheduled toileting, habit training, and prompted voiding. Routine or scheduled toileting should be offered to incontinent patients on a consistent schedule. This technique is recommended for patients who cannot participate in independent toileting. (Strength of Evidence = C.)

Routine or scheduled toileting is provided by the caregiver on a fixed schedule at regular intervals. The caregiver takes the patient to void every 2-4 hours including at night. The goal is to keep the patient dry. No systematic effort is made to motivate the patient to delay voiding and resist urge, unlike in bladder retraining. In an uncontrolled, descriptive study of 161 male institutionalized patients, 20 patients who received a 4-week regimen of toileting every 2 hours eight times per day experienced an 85-percent improvement and were incontinent less than 20 percent of the time. In an uncontrolled, descriptive study of 20 females aged 24-94 years who were instructed to void every 2 hours regardless of urge for a period of 2 weeks, patients reported a 79-percent success rate. Burgio, Stutzman, and Engel (1989) studied 20 men postprostatectomy who followed a 2-hour voiding program for 2 weeks and reported a 33-percent increase in urgency, 29-percent decrease in stress UI, and no change in continual leakage.

Habit training is recommended for patients for whom a natural voiding pattern can be determined. (Strength of Evidence = B.) Habit training is toileting scheduled to match the patient's voiding habits. One controlled study of habit training identified voiding patterns of 51 nursing home residents with an electronic monitoring device. The nursing home staff were taught to toilet the residents during the periods of greatest voiding frequency based on individual patterns identified by monitoring. A significant reduction in UI occurred during the 3-month intervention in 86 percent of the subjects, with one-third of this group showing 25 percent or greater improvement over baseline compared with an increase in UI observed in the control group. In addition, the volume of urine loss decreased significantly in the experimental group only. No side effects of habit training were reported. Nursing staff compliance was a problem, however, because of resistance to changes in care routines.

Prompted voiding is recommended in patients who can learn to recognize some degree of bladder fullness or the need to void, or who can ask for assistance or respond when prompted to toilet. Patients who are appropriate for prompted voiding may not have sufficient cognitive ability to participate in other, more complex behavioral therapies. (Strength of Evidence = A.) The three major elements of prompted voiding are as follows:

- Monitoring -- The patient is checked by caregivers on a regular basis and asked to report verbally if wet or dry.
- Prompting -- The patient is asked (prompted) to try to use the toilet.
- Praising -- The patient is praised for maintaining continence and for trying to toilet.

Prompted voiding has been shown to be effective in dependent or cognitively impaired nursing home incontinent patients. Used as a supplement to habit training, prompted voiding reinforces discrimination of continence status,

the need to urinate, and requests for toileting assistance from caregivers. Four clinical trials, three controlled and one uncontrolled, evaluated prompted voiding in nursing homes. The combined trials used prompted voiding for 251 residents and demonstrated significant reductions in incontinence with no reported side effects. An average reduction of 0.8-1.8 incontinence episodes per patient per day was reported. In contrast, the baseline number of incontinence episodes in control group subjects of approximately 4.5 times per 12-hour period remained unchanged over the course of the clinical trial. Residents with lower voiding frequencies (less than four in a 12-hour period) and those who toileted appropriately more than 75 percent of the time during a brief 2- to 6-day prompted voiding trial were the most likely to show long-term benefits with prompted voiding. A clinical trial in seven nursing homes reported that nursing staff were able to maintain improved resident continence levels for 6 months in 76 residents who were identified as highly responsive to prompted voiding. An earlier study showed that the behavioral training resulted in an estimated 76 percent savings per day per patient, and the investigators recommended that such training be instituted early after admission to maximize savings. Because nursing home staff administer the prompted voiding and habit training protocols, program success relies on training, compliance, and incentives for active staff participation. A 3-hour prompted voiding schedule can improve dryness in residents with mild to moderate UI

Bladder Training Bladder training is strongly recommended for management of urge (DI) and mixed incontinence. Bladder training is also recommended for management of SUI. (Strength of Evidence = A.) Bladder training (also termed "bladder retraining") has many variations but generally consists of three primary components:

- Education.
- Scheduled voiding with systematic delay of voiding.
- Positive reinforcement.

The education program usually combines written, visual, and verbal instruction that addresses the physiology and pathophysiology of the lower urinary tract. A bladder training program requires the patient to resist or inhibit the sensation of urgency, to postpone voiding, and to urinate according to a timetable rather than according to the urinary urge (McCormick and Burgio, 1984). Bladder training may involve tactics that help distend the bladder, such as adjustment in fluid loads and delayed voiding to provide progressively larger voiding volumes and longer intervals between voids/ Initially, the interval goal is usually set between 2 and 3 hours or determined by the patient's present interval, and is not enforced during sleeping hours. The voiding schedule progressively increases the interval between mandatory voids with concomitant distraction or relaxation techniques. The patient is thus taught to delay voiding when the urge to void occurs. If the patient is unable to delay voiding between scheduled toileting times, the schedule is adjusted and the interval time is reset from the time of the last void. Another method is to keep the prearranged schedule and disregard the unscheduled void between schedules. The training may continue for several months, during which time the therapist provides positive reinforcement and instruction.

Bladder training has been used primarily to manage UI caused by DI. This form of training has few side effects but is difficult to implement in cognitively impaired persons. It may not be successful in frail, elderly patients. Several reports demonstrate that bladder training is effective in reducing UI. A controlled, randomized study of 131 women with sphincteric incompetence and unstable detrusor function, 123 of whom had some follow-up data. Subjects receiving treatment participated in a bladder training program that included behavioral strategies to decrease urge, patient education, and a schedule of voiding. Of the 60 women in the treatment group, 12 percent became dry and 75 percent had at least a 50-percent reduction in the number of incontinent episodes. The magnitude of the effect was somewhat larger in the women with DI. The effect of bladder training was maintained after 6 months. Control subjects did not have significant changes in incontinent episodes. To date, no urodynamic variable has been shown to relate directly to the observed beneficial clinical effects.

Pelvic Muscle Rehabilitation PME's may be used alone or augmented with bladder inhibition biofeedback therapy or with vaginal weight training. **Pelvic floor electrical stimulation** is another method of pelvic muscle rehabilitation. Health care providers must teach patients the correct method of distinguishing and contracting the pelvic muscles through digital vaginal examination to verify appropriate muscle use, verbal feedback, or use of vaginal weights and biofeedback therapy to ensure accurate performance.

Pelvic Muscle Exercise Teaching women PME's may prevent UI. (Strength of Evidence = C.) Teaching exercises to strengthen pelvic muscles may decrease the incidence of UI. (Strength of Evidence = C.) PME's are strongly recommended for women with SUI. (Strength of Evidence = A.) PME's are also recommended in men and women in conjunction with bladder training for urge incontinence. (Strength of Evidence = B.) PME's may

also benefit men who develop urinary incontinence following prostatectomy (Strength of Evidence = C.) PME, also called Kegel exercises and pelvic floor exercises, are performed to strengthen the voluntary periurethral and perivaginal muscles (i.e., voluntary urinary sphincters and levator ani) that contribute to the closing force of the urethra and to the support of the pelvic visceral structures. The first step in pelvic muscle re-education is to establish better awareness of pelvic muscle function. PMEs are performed by "drawing in" or "lifting up" of the perivaginal muscles and anal sphincter as if to control urination or defecation with minimal contraction of abdominal, buttock, or inner thigh muscles. Patients are generally told to sustain a contraction for at least 10 seconds, followed by an equal period of relaxation. The exercises should be performed about 30-80 times a day for at least 8 weeks and may need to be continued indefinitely. Elderly patients may require a longer time to train. In general, an individualized program of exercises and repetitions should be tailored to enhance muscle strength progressively. To condition the muscle to contract with increases in intra-abdominal pressure, patients should be taught to contract the pelvic muscles before and during situations when leakage may occur. The specific effects of PMEs on actual lower urinary muscle function is not completely understood; some studies show a relationship between changes in various measures of pelvic floor strength, such as anal sphincter strength or maximum urethral closure pressure, and reduction in incontinence.

PMEs are indicated for women with stress incontinence and can reduce urgency and prevent urge UI. They may be effective in reducing incontinence following prostatic surgery in men, but to date have only been tested for postprostatectomy in conjunction with a biofeedback component. PMEs are effective in reducing UI even after multiple surgical repairs in women. The effects of PME alone have been well documented in the medical literature. A summary of outcome findings from well-conducted studies follows. A study of 65 women 35-75 years of age (mean age 51.3) and obtained a 62-percent reduction in UI episodes, and Ferguson, McKey, Bishop, et al. studied 20 women and demonstrated a 56- to 58-percent reduction in leakage as measured by 24-hour pad test using audiotape instruction in PME. Telephone contact and ongoing use of a bladder record may have contributed to the greater success found in these studies compared with others using a one-time instruction session. To date, the most effective use of PME has been reported in an uncontrolled study, providing 20 sessions of PME and other behavioral strategies and an intensive home program for a total of 10 contact hours to 20 women aged 35-65 years (mean age 50.8). In addition to a 95-percent reduction in incontinent episodes, significant changes were also reported FUL and MUCP at rest and during maximal voluntary contraction. A significant clinical benefit was consistent with changes in several physical measures of bladder function.

In a randomized clinical trial comparing PME and phenylpropanolamine hydrochloride (PPA), PME was found to be an effective alternative treatment for SUI comparable to PPA. Of the 54 subjects who completed the exercise program and the 64 who completed the drug protocol, 77 percent of the exercise subjects and 84 percent of the drug subjects reported improvement. The PME protocol involved 6 months of active PME taught with only written instruction, followed by monthly monitoring visits. The PPA was administered in doses of 50 mg daily for 2 weeks, increasing to twice daily if wetting continued. Adherence to the drug treatment was greater than to the exercise protocol. Indications are that the intensity of the exercise program affects physiological and functional outcomes. Bo, Hagen, Kvarstein, et al. (1990) found that 52 subjects of mean age 45.9 years (range 24-64) randomized into a group receiving ongoing guidance in performing maximum contractions of the pelvic muscle that increased in intensity over 6 months reported significantly greater reduction in incontinence and changes in physiological measures of pelvic floor strength compared with a group that received only a single session of instruction and a home exercise program. The group receiving the ongoing instruction reported a 60.1-percent cure/improvement rate compared with 17.3 percent attained in the home exercise group. This work also indicates a possible systematic relationship between symptom reduction and objective physical changes.

There is evidence that pelvic muscle re-education has the potential to change muscle physiology. Standards for assessment of change in pelvic muscle function have yet to be established, however. PME also appears to be effective in the treatment of older adults. Flynn, Cell, and Luisi (1994) provided treatment for transient UI in 37 older adults receiving home nursing care (mean age 76) and behavioral strategies that included education in the maintenance of bowel regularity, bladder and habit training, fluid intake management, and PME. An 82.4-percent decrease in UI was attained with an average of five nursing visits. Because those patients with transient UI were not separated in the final analysis, the specific effect of the behavioral treatment is difficult to determine. Nonetheless, this report and others demonstrate the overall effectiveness of a well-directed nursing program, which includes PME for UI in the homebound and long-term chronically ill patients.

Summary of findings. Evidence demonstrates that patients require repeated guidance over an extended period of time to derive optimal benefit from PME. Kegel himself recommended that patients be seen weekly to ensure that the exercises were being performed correctly. Further controlled studies are needed to demonstrate the most

efficient method of teaching PME, exercise prescription, and the conditions in which biofeedback provides an added benefit to PME alone. It should also be noted that the majority of the research on PME is in women only.

PME and Bladder Inhibition Augmented by Biofeedback Therapy Pelvic muscle rehabilitation and bladder inhibition using biofeedback therapy are recommended for patients with stress UI, urge UI, and mixed UI. (Strength of Evidence = A.) Some type of biofeedback device is often used to assist patients to gain function and pelvic muscle awareness. The aim of biofeedback therapy, which uses electronic or mechanical instruments to relay information to patients about their physiologic activity, is to improve bladder dysfunction by teaching people to change physiologic responses that mediate bladder control. Auditory or visual display of this information forms the core of biofeedback procedures. Biofeedback for UI typically uses single measurement (surface, needle, vaginal, or anal probe) EMG or manometric methods. Biofeedback using multimeasurement feedback methods involves simultaneous measurement of pelvic and abdominal/ detrusor muscle activity. Biofeedback should be used in conjunction with other behavioral techniques such as PME and bladder training. As with all of the behavioral techniques, successful application of biofeedback depends greatly on the knowledge and skill of the health care provider, whose knowledge must include familiarity with evaluation techniques, anatomic and physiologic correlates of the different forms and symptoms of bladder dysfunction, instrumentation, and behavioral principles that guide the procedure. Studies on the various applications of biofeedback combined with behavioral treatment report a range of 54-87 percent improvement in incontinence across various patient groups using different biofeedback and behavioral procedures.

Some biofeedback protocols use only one measure for reinforcement of pelvic muscle contraction, whereas others use up to three, and include measures of abdominal and detrusor activity. The biofeedback protocol that has been associated with the largest and most consistent symptom reduction is one that reinforces pelvic muscle contraction concurrently with inhibition of abdominal and detrusor contraction. Reports using this multimeasurement method show a 75.9-82 percent reduction in UI across six studies involving 166 subjects. The presumed benefit of the multimeasurement procedure is that it reinforces pelvic floor contraction directly with moment-to-moment feedback, which characterizes for the patient the quality and intensity of the contraction. Without biofeedback, weak pelvic muscles may provide limited kinesthetic feedback to the desired contraction, and as a result the patient uses an attenuated internal reference to upgrade muscle contractions. Combining bladder and sphincter biofeedback also allows teaching pelvic muscle contraction in response to increasing bladder volume and observed detrusor activity. In a controlled study, Burgio, Robinson, and Engel (1986) found that 13 subjects (mean age 47.9) receiving multimeasurement biofeedback reduced incontinence by 75.9 percent compared with a 51-percent reduction obtained in 11 subjects (mean age 40.7) who received only verbal feedback and instruction for PME with digital palpation.

The multimeasurement biofeedback method has also been used successfully in the treatment of UI in postprostatectomy patients with urge and intermittent stress incontinence. However, another study demonstrated that when subjects complained primarily of urge incontinence, no benefit was obtained with the addition of biofeedback to behavioral training and PME, which was provided by a well-trained clinician over an average of five clinic sessions. The results of this study should be interpreted with caution, however, because the groups differed in severity before treatment. Several studies have also demonstrated significant reductions in UI associated with neurologic disease and in the frail elderly using a combination of multimeasurement biofeedback and other behavioral techniques such as bladder training. Because multimeasurement biofeedback can provide specific reinforcement for pelvic muscle contraction that is isolated from counterproductive abdominal contraction, it is assumed that awareness of pelvic muscle contraction can be achieved more efficiently than from vaginal palpation alone. In contrast to multimeasurement methods, the reduction in number of pad changes per 24 hours ranged from 43 to 54 percent when single-measurement biofeedback is used, when excluding a subgroup who had received only one biofeedback session. This improvement was attained in an approximate average of 11 sessions (0.5 to 1.5 hours each).

Another study used single-channel biofeedback over six weekly clinic visits and a home trainer with which the subjects practiced daily. These subjects demonstrated an 87-percent reduction of leakage on pad test, suggesting that a home training device may provide an added benefit to clinic biofeedback visits, especially when only single-channel biofeedback is used. In a randomized controlled study, Burns, Pranifoff, Nochajski, et al. (1993) studied 135 women (age range 55-75 years) with primary stress incontinence in three groups. One group received PME, and another group received single-measurement EMG biofeedback to perivaginal contraction for 20 minutes per week. The two treatment groups demonstrated a 54-61 percent reduction in incontinent episodes, compared with a 6-percent reduction of incontinence in the control group, but no difference between the two treatment groups was found. The improvements were maintained over a 6-month follow-up, and patients with moderate-to-severe

symptoms showed even more improvement in the post-treatment phase. This study demonstrated that PME reduces incontinence and provided evidence that symptom severity has a role in response.

Further research is needed to determine which biofeedback protocols ensure that optimal outcomes are achieved in individual conditions and what methods provide the most valid measures of pelvic muscle function. The multimeasurement biofeedback appears to produce greater reduction in incontinence compared with PME alone or single measurement biofeedback. It is not known, however, to what degree detrusor or intra-abdominal pressure biofeedback individually contributes to the outcomes reported.

Summary of findings. Overall, the literature indicates that PME and other behavioral strategies, with or without biofeedback, can "cure" or reduce incontinence. Maximum benefit is derived from any pelvic muscle rehabilitation and education program when ongoing reinforcement and guidance are provided. Also, the intensity of the exercise program seems to influence both functional and physiological outcomes, and multimeasurement biofeedback protocols seem to yield the greatest and most consistent reductions in UI.

Pelvic Muscle Exercises Augmented with Vaginal Weight Training: Vaginal weight training is recommended for SUI in premenopausal women. (Strength of Evidence = B.) Specially designed vaginal weights for strengthening the pelvic muscles can augment PME. The patient receives a set of vaginal weights of identical shape and volume but of increasing weight (20-100 grams). As part of a structured progressive resistive exercise program, women insert the weight intravaginally, with the tapered portion resting on the superior surface of the perineal muscle and attempt to retain it by contracting the pelvic muscles up to 15 minutes. The weight is worn while the patient is ambulatory, and the exercise is done twice daily. The hypothesized mechanism of action is that the sustained contraction required to retain the weight increases the strength of the pelvic muscles, and the weight is assumed to provide heightened proprioceptive feedback to desired pelvic muscle contraction. Available literature on this technique includes observations made in premenopausal women with SUI. Initial observations from four studies including 103 premenopausal women indicate subjective "cure" or greatly improved status of 68-80 percent after 4-6 weeks of treatment. Objective outcome measures included reduction of urine loss on pad test, improvement in ability to hold heavier weights intravaginally, increased pelvic muscle strength (perineometer), and significant reduction in incontinence episodes. There were minimal or no adverse reactions. However, in several studies, PMEs were performed at the same time. Although vaginal weight training may be useful in the treatment of stress incontinence, issues of applicability to other populations, particularly postmenopausal women with pelvic organ prolapse or other comorbid conditions, must be evaluated in terms of treatment protocols and long-term effects.

Pelvic Floor Electrical Stimulation: Pelvic floor electrical stimulation has been shown to decrease incontinence in women with SUI. (Strength of Evidence = B.) Pelvic floor electrical stimulation may be useful for urge and mixed incontinence. (Strength of Evidence = B.) Pelvic floor electrical stimulation (nonimplantable) produces a contraction of the levator ani, external urethral and anal sphincters, accompanied by a reflex inhibition of the detrusor; this activity depends on a preserved reflex arc through the sacral micturition center (Vodusek, Plevnik, Vrtacnik, et al., 1988). Nonimplantable pelvic floor electrical stimulation uses vaginal or anal sensors or surface electrodes. Adverse reactions are minimal and include pain and discomfort. Studies vary regarding the type and placement of electrodes; frequency, duration, and amplitude of voltage; and whether the stimulation was phasic, intermittent, or continuous. Several of these studies address long-term follow-up with reports that the effects for cured or improved patients ranged from 54 to 77 percent.

Two randomized controlled trials have been conducted. Using active and placebo perianal surface patch neurostimulation for SUI in patients, (Blowman, Pickles, Emergy, et al. 1991) reported a "cure" or improvement rate of 86 percent in the active group (N=7) and 33 percent in the placebo group (N=6). Electrical stimulation was not used as a single therapy, however; both groups also received instruction in PME. Using active and inactive vaginal plug devices in 52 women with SUI, Sand, Richardson, Staskin, et al. (1995) reported objective "cure" or improvement in 48 percent of the active device group and in 13 percent of the placebo group. Active device patients had significant improvements in UI episodes, leakage volume, and vaginal muscle strength and in subjective improvement measures when compared with the placebo group. In other studies with similar settings, anal or vaginal plug devices were used for maximal electrical stimulation for 4 weeks to 3.5 months, 20 minutes to 20 hours/day. "Cure" or improvement rates ranged from 48 to 94 percent in 842 patients with stress, urge, or mixed incontinence. The effects of therapy were sustained 6 weeks to 2 years in 54-77 percent of patients, especially if patients continued to do PME after treatment. One study of cognitively impaired patients in a nursing home showed no significant effect of stimulation, with a trend toward increased wetness.

Summary of findings. Research indicates that pelvic floor electrical stimulation can significantly reduce UI in women with SUI, and may be effective in men and women with mixed and urge UI. Stimulation may be effective when augmented with other pelvic muscle rehabilitation therapies. Minimal adverse side effects occur with this treatment. Treatment using stimulation requires monitoring by a health care provider to determine effectiveness. Further research is needed to determine the efficacy of pelvic floor stimulation used alone or in combination with other therapies. Standardization of the parameters of the techniques used, such as that proposed by the International Continence Society, is necessary to allow further comparison of study results.

² Also see: The effectiveness of surgery for stress incontinence in women: a systematic review. N.A. Black and S.H. Downs, Health Services Research Unit, Department of Public Health and Policy, London School of Hygiene and Tropical Medicine, London UK, in *British Journal of Urology*, 1996 78: 497-510. Authors concluded that there is an urgent need for large, rigorous, prospective studies on the effectiveness of surgery for stress urge incontinence in women. Until then, recommendations as to best clinical practice cannot be based upon scientific evidence. Due to methodological shortcomings, conclusions are speculative, but it appears that colposuspension may be more effective and longer-lasting than anterior colporrhaphy and needle suspension. There is little information on sling procedures. Data on complications is sorely lacking in these studies. Repeat operations appear to be less successful than the first operation, but this conclusion may be based upon confounding factors. An editorial (page 510) suggests that comparisons are difficult because patient characteristics drive selection of operation. Therefore, there is no one "best" surgery, but possibly a best operation for each particular patient with stress incontinence.

³ Based on the National Blue Cross Blue Shield Association policy 7.01.17 12/95, including a literature review from 1/94 through 1/95. And a 1994 TEC assessment on periurethral injections for incontinence (vol 9 no. 14). Glutaraldehyde cross-linked (GAX) collagen was FDA-approved 9/93 for use in stress urinary incontinence due to intrinsic sphincter deficiency in patients with no improvement in incontinence for at least 12 months. Evidence based on 1-2 year data suggest that at least 78% of females and 69% of males achieved dryness or improvement in symptoms. Only 3% noted deterioration in continence. Most adverse effects were mild and were limited to the immediate post-op period. Studies with sling procedures suggest about 80% of women were either dry or improved. Artificial urinary sphincters resulted in about 83% dryness. Therefore, collagen implantation appears to offer similar benefits, at least short term, while offering an improved side effect profile.

⁴ Based on CMS (Centers for Medicare & Medicaid Services) guidelines CIM 65-9, October 1996. Medicare policy is developed separately from BCBSMA policy. While BCBSMA policy is based upon scientific evidence, Medicare policy incorporates scientific evidence with local expert opinion, and governmental guidelines from CMS (Centers for Medicare & Medicaid Services) and the US Congress. While BCBSMA and Medicare policies may differ, our Blue Care 65 patients must be offered the same services as Medicare offers. In many instances, BCBSMA policies offer more benefits than does Medicare policy.

For Medicare's policy see CIM 65-9 at the following web address:

http://www.hcfa.gov/pubforms/06_cim/ci60.htm#_1_17a

⁵ Based on the American Medical Association's *Tech Brief* on Collagen Implants for Incontinence (November 1995). The most common cause of stress incontinence is hypermobility resulting from displacement of the urethra and bladder neck during exertion. Loss of pelvic support leading to hypermobility is called Type 2 stress incontinence. Another type, intrinsic urethral sphincter deficiency (ISD, Type 3 stress incontinence) is caused by damage or inadequacy to urethral continence mechanisms. Such damage may occur following stress incontinence surgery in women, or in men following urethral or prostate surgery (such as radical prostatectomy). Only rarely does Type 3 occur as a result of congenital sphincter weakness (myelomeningocele, epispadias). Less frequent causes include pelvic muscle denervations from sacral cord lesions, radiation therapy, and pelvic trauma. Few patients have pure ISD, most also have hypermobility, detrusor instability, and other problems. Periurethral or transurethral injections do not improve anatomic causes of incontinence such as hypermobility, but may be appropriate for patients with relatively pure intrinsic sphincter incontinence, especially those who fail previous attempts at surgical repair. Bulking with collagen may also be useful as an adjunct to other surgical procedures in patient with both types of stress incontinence. Patients with low urethral closing pressure in the most premaxilla portions of the urethra are good candidates for collagen injection therapy. Best results occur in patients with relatively pure ISD and minimal hypermobility, with adequate bladder capacity and no detrusor problems. Candidates should demonstrate urodynamic (and/or radiographic) failure of the most proximal portion of the urethra to close at rest, in the absence of a detrusor contraction. The Valsalva leak point pressure (abdominal pressure at which fluid instilled in the bladder exits the urethra) is a convenient method of determining

ISD. Appropriate candidates have low leak point pressure. Most have had previous surgery (radical prostatectomy, suspension procedures in women). Mild detrusor instability does not preclude use of collagen. Patients should have shown no improvement in incontinence over 12 months.

Summary: the safety and effectiveness of collagen implants for Type 3 stress incontinence (post-prostatectomy, female stress incontinence) was considered promising by the expert panel.

⁶ Based on 9/97 TEC (Technology Evaluation Center) scientific assessment on medical literature up to 8/97 on biofeedback in the treatment of adult urinary incontinence. TEC reviewed 6 controlled trials comparing behavioral treatments alone to behavioral treatments with biofeedback. These trials were small (n=298 total, largest single study n=135). Conclusions were conflicting. 4/6 trials reported no significant differences between control and biofeedback groups, related to the main outcomes of interest. Of these four negative studies, 3 reported non-significant trends in favor of biofeedback and/or differences in intermediate outcomes (eg. perineal muscle strength). The remaining 2 studies suggested a benefit, though in one of these two, no tests of statistical significance were done. All trials had low power to detect possible small differences in outcomes. The authors of the largest trial concluded that much larger patient numbers would be required to show statistical significance for the small magnitude of changes seen. There is insufficient evidence to demonstrate any added benefit from biofeedback in addition to standard therapy.

⁷ Based on the 10/98 TEC (Technology Evaluation Center) assessment of medical literature through 7/98 on sacral nerve stimulation for urge incontinence. The Medtronic® Interstim Sacral Nerve Stimulator™ is FDA-approved for urinary urge incontinence in patients who have failed or could not tolerate more conservative treatments.

Efficacy: One multi-center randomized controlled trial and several small series of patients with a long history of incontinence, having failed extensive previous therapy, with a high baseline frequency of incontinence, were studied. None of these patients had urge incontinence due to neurologic conditions. By using a peripheral nerve evaluation test, about 60% of eligible patients were considered eligible for the implant. There was a large magnitude of improvement, with about 50% of the patients experiencing a “cure”, and overall 75% showing significant clinical improvement (50% or more reduction in incontinence frequency). Beneficial effects appear to be maintained for at least 24 months. Furthermore, the effects of the device appear to be reversible, since levels returned to baseline once the device was turned off.

Adverse events: The rate of adverse events was high: about 20% experienced an event during peripheral nerve evaluation testing, and 50% experienced one or more events following implantation. Most of these are minor, and resolve with treatment, or device revision: post-implant pain, infection, adverse changes in bowel function, lead migration, and electrical shock sensation. About 1/3 of patients needed additional surgical procedures (revision/replacement).

Alternatives: the chief alternative is surgery, such as enterocystoplasty; using the AH CPR definition of a cure rate for this procedure, only about 38% are cured; a larger percentage achieve continence, but must use intermittent catheterization. Procedural complications occur in 54% of patients. Other alternatives, such as urinary diversion, carry high rates of infection. Newer surgeries are under investigation.

⁸ Also see, Behavioral vs Drug Treatment for Urge Urinary Incontinence in Older Women, JAMA, December 16, 1998 vol 280, number 23. In a randomized clinical trial of biofeedback-assisted behavioral treatment for urinary incontinence compared with standard pharmacological treatment, biofeedback-assisted behavioral training was found to be safe and effective conservative intervention compared to drug therapy. Behavioral intervention had the advantage to reduce incontinence without the adverse effects that are common with pharmacological agents. Behavioral treatments have been shown to improve bladder control by teaching new skills or habits, and could be made more readily available to patients as a first-line treatment for urge or mixed incontinence.

⁹ The Medtronic® Interstim Sacral Nerve Stimulator™ also received FDA-approval in February 1999 for urinary retention and symptoms of urgency/frequency.

¹⁰ Based upon the 3/00 TEC (Technology Evaluation Center) assessment of pelvic floor electrical stimulation (PFES) for patients with urinary incontinence. This report examined medical literature from 1966 through April 2000 on stress incontinence and urge incontinence. PFES for post-prostatectomy incontinence was also addressed. PFES was compared with placebo treatment and other conservative treatments including PME (pelvic muscle exercises), bladder training, PME using vaginal cones, medication), and as an adjunct to PME.

FDA status: The FDA has cleared several brands of pelvic floor electrical stimulators for commercial use under the 510K.

Stress incontinence

11 controlled trials were examined; they did not provide strong and consistent evidence that PFES reduced the frequency and severity of incontinent episodes. 5 trials (n=243), 4 of which were randomized, compared PFES to sham in stress incontinence patients. An additional 5 trials (n=260) compared PFES to PME or to vaginal cones. One trial compared PFES plus PME to PME alone. These trials were small (range 7-36 per arm) relative to the population with stress incontinence, and the majority of these studies were inadequately powered to detect a difference or to even demonstrate equivalence.

Placebo comparisons: 3 trials comparing PFES to placebo reported statistically significant results favoring PFES: **Sand et al (1995):** Although randomized and double-blinded, differences may have been influenced by a high degree of variability in incontinent episodes in the control group, comprising only 17 patients. **Yamagishi et al (1997):** (n= 30 women) reported high rates of improvement/cure in the PFES group. This trial does not appear to be randomized, hence it may be prone to selection bias. **Laycock and Jerwood (1993):** This single blind, randomized trial (n= 30 women) found a significant % reduction in grams of urine leaked in the PFES group compared to placebo. However, there is potential for both performance and attrition bias.

Alternatives: Five randomized controlled trials (n=260) compared PFES to alternative conservative treatment like PME or vaginal cones. **Bo et al (1999):** Only this trial reported statistically significant results. Four-armed and single-blinded, this trial found that a structured PME program (n=29) was superior to PFES (n=32) on the % improvement on a standardized pad test. There was a 78.2% decrease in the PFES group (p=0.02). This trial also compared PFES (n=32) with vaginal cones (n=29) and found no significant difference between groups. In the unblinded trials, no significant group differences were found.

Summary: The large amount of variability in the delivery of PFES across studies limits conclusions; there was no standardization of PFES delivery among studies. Treatment varied in location (home vs. office), time of administration (once a day, multiple time/day for varying periods), probe type and location, and frequency/amplitude of stimulation. It is possible that such variations alter the outcomes across the studies.

Urge incontinence

Brubaker (1997): Two randomized controlled trials studied PFES in women with urge incontinence (n=66) or mixed incontinence (n=33). No conclusions can be drawn from these trials. The placebo-controlled trial did not report improvement and cure measured by voiding diaries or pad testing. Only pre- and post-intervention urodynamic testing was noted, without tests of statistical significance between treatment and control groups. No significant difference was found on the trial comparing PFES to an anticholinergic drug; it was inadequately powered to detect a difference or to demonstrate no difference, because of small sample size.

Post-prostatectomy

Moore (1999): One study compared the combination of PFES and PME to PME alone. A randomized trial of patients (n=63) with incontinence more than 8 weeks post-prostatectomy compared PFES plus PME to PME alone and found no difference between groups. Thus, this study did not demonstrate that the addition of PFES to PME improves outcomes.

¹¹ Based upon the 3/00 TEC (Technology Evaluation Center) assessment of biofeedback as an aid to performing pelvic floor muscle exercise. This report examined medical literature from 1976 through April 2000 on stress, urge, and post-prostatectomy incontinence.

FDA status

Biofeedback is not specifically subject to FDA approval. Monitoring devices used for biofeedback include manometric or electromyographic monitors, which may or may not be subject to FDA approval.

Health Outcomes

8 controlled trials were identified that concurrently compared PME plus biofeedback to a control group of PME alone. 1 trial included a comparison to a no-treatment group. Most of these trials reported on patients with stress incontinence, and one each on patients with urge and post-prostatectomy incontinence.

Stress incontinence (Burns 1993; Ceresoli 1993; Glavind 1996; Bergham 1996; Shepherd 1983; Burgio 1986): Bias limits drawing conclusions from these trials. For example, in one of these trials, although randomized, results are vulnerable to both performance and attrition bias: treatment intensity was greater in the PME plus biofeedback group, yet dropouts were greater in the PME alone arm. Another trial, while stratified to balance groups by age and incontinence frequency, was not randomized. It is conceivable that there is some additional benefit to biofeedback, and that the studies that found no significant difference lacked sufficient power due to small sample size. Yet, in at least one of these trials, there was adequate power to detect a difference. It is conceivable that biofeedback is effective for a subset of patients who have difficulty performing PME, and that this benefit is not apparent when the whole group of patients is considered; however, the available evidence cannot distinguish among these possibilities. This evidence fails to demonstrate that the addition of biofeedback to PME is better than PME alone. Of note, Berghman's systematic review and data synthesis concluded that biofeedback does not offer additional benefit to pelvic floor muscle exercise alone.

Other: For urge and post-prostatectomy incontinence, only 2 small trials were identified (**Burton 1988; Franke 2000**). In both studies, there was no statistically significant improvement in outcomes for the biofeedback plus PME group, compared to PME alone. Therefore, the evidence is insufficient to conclude that adding biofeedback to PME improves health outcomes.

Summary: Whether or not biofeedback improves outcomes more than PME alone cannot be determined from this body of evidence. While it is possible that there is some additional benefit to biofeedback, the data from these controlled trials are insufficient to demonstrate it. If so, this benefit is probably small, and may not be clinically relevant. Larger randomized, controlled trials would be required to answer this question conclusively.

¹² Burgio 1998. Behavioral vs drug treatment for urge urinary incontinence in older women; JAMA, 280:1995-2000: This study (n=197 women) concluded that biofeedback-assisted pelvic floor muscle exercises were superior to drugs and/or placebo for patients with urge incontinence. However, this comparison does not answer the question: Is biofeedback more useful than pelvic floor muscle exercise alone? From this study, it is not possible to determine whether pelvic floor muscle exercises alone would have fared as well against placebo and/or drugs. A well-designed research study would compare pelvic floor muscle exercises with and without biofeedback in order to answer the question about the additional value, if any, of biofeedback.

A study by McDowell et al. evaluated outcomes between biofeedback-assisted pelvic floor muscle exercise vs. a control group on a waiting list. The biofeedback-assisted group had better outcomes; this does not isolate the biofeedback component; it is conceivable that pelvic floor muscles alone accounted for the differences.

¹³ Based upon the 9/00 TEC (Technology Evaluation Center) assessment of sacral nerve stimulation for refractory urinary urgency/frequency in adults. This report examined medical literature from 1966 through July 2000. See also Blue Cross Blue Shield Association national policy 7.01.69, issued 8/18/00.

Urinary Urgency/Frequency: Data consisted of 1 randomized controlled trial, a long-term single-arm cohort study and data submitted to the FDA as part of the approval process. In the multicenter randomized trial of (n=581) patients, 220 patients had significant urgency-frequency symptoms. **Summary:** After 6 months, 83% of patients with urgency-frequency symptoms reported increased voiding volumes with the same or reduced degree of frequency. At 12 mos., 81% reached normal voiding frequency. Compared to a control group, patients with implants reported improvements in quality of life.

Urinary retention: In the randomized trial noted above, 177/581 patients had urinary retention. Patients with urinary retention reported improvements in terms of volume catheterized per catheterization, a decrease in the number of catheterizations per day and increased total voided volume per day. **Summary:** At 12 mos. post-implant, 61% had eliminated the use of catheterization. Patients with implants also reported improved quality of life.

¹⁴ Based upon the Blue Cross Blue Shield Association national policy 1.01.17, issued 12/15/00.

¹⁵ Based upon the Blue Cross Blue Shield Association national policy 2.01.27, issued 12/15/00.

¹⁶ In accordance with the September 2001 Medicare B Resource and CMS guidelines, CIM 60-24. See also: www.medicarenhic.com and www.hcfa.gov.

Failed trial of PME training: Defined by Medicare as “no clinically significant improvement in urinary continence after completing 4 weeks of an ordered plan of pelvic muscle exercises designed to increase periurethral muscle strength.”

¹⁷ Local Medicare Policy was retired 3/4/03. To view go to http://www.cms.hhs.gov/med/viewlmp.asp?lmp_id=7168&lmp_version=6&show=all

¹⁸ Based on the 2002 Blue Cross Blue Shield Association National policy 1/01.17. The 2002 analysis, which included review of the medical literature published from 2000 through October 2002, did not identify full-length peer-reviewed papers reporting results of a randomized trial. According to the National policy, the policy statement is unchanged because the available data is insufficient to change the conclusion of the 2000 TEC assessment.

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- Gillling PJ, Kennett KM, Bell D. A double-blind randomized trial comparing magnetic stimulation of the pelvic floor to sham treatment for women with stress urinary incontinence.
- Abstract presented at the European Association of Urology, Geneva, Switzerland, April 7-10.

¹⁹ Based on the 2002 Blue Cross Blue Shield Association National policy 2.01.27 and the 2000 Technology Evaluation Center report. The National policy noted that the conclusions of the 2000 TEC assessment were similar to the 1997 assessment stating that the evidence is not sufficient to demonstrate that the addition of biofeedback is superior to PME alone.

²⁰ Based on the 2004 Blue Cross Blue Shield Association National Policy 2.01.58. The national policy notes a literature search of MEDLINE identified 1 published study of the Secca™ System. This system was FDA approved in 2002 and has been approved with the following labeled indication: The Secca™ System is intended for general use in the electrosurgical coagulation of tissue and is intended for use specifically in the treatment of fecal incontinence in those patients with incontinence to solid or liquid stool at least once per week and who have failed more conservative therapy. It concluded that the published data are inadequate to permit scientific conclusions due to the small size of the trial and the lack of a control group.

Blue Cross Blue Shield Association National policy 2.01.58 was issued 3/05 after an updated literature review performed for the period of 2004 failed to identify any additional published studies that would prompt reconsideration of the policy statement, which remains unchanged.

References reviewed included:

- Efron JE, Corman ML, Fleshman J et al. Safety and effectiveness of temperature-controlled radio-frequency energy delivery to the anal canal (Secca procedure) for the treatment of fecal incontinence. *Dis Colon Rectum* 2003; 46(12):1606-18.

- www.curonmedical.com/products/secca_datasheet.html
- Rothbarth J, Bemelman WA, Meijerick WJ et al. What is the impact of fecal incontinence on the quality of life. *Dis Colon Rectum* 2001; 44(1):67-71.

Based on Blue Cross Blue Shield Association National Policy 2.01.58 issued 12/05.

2005 Update: A search of the literature for the period of 2004 through October 2005 failed to identify any additional published studies that would prompt reconsideration of the policy statement, which remains unchanged.

²¹ Based on 2004 Blue Cross and Blue Shield Association National Policy 1.01.17 updated 4/04. The national policy statement is unchanged, and the policy was updated with additional references. In February of 2004, a review of the literature published since the 2000 TEC Assessment identified few new reports that met study selection criteria, and those identified do not change its conclusions.

Wille and colleagues reported on the results of a trial that randomized post-prostatectomy patients into 1 of 3 groups: pelvic floor exercises alone, exercises plus stimulation, and exercises in conjunction with both stimulation and biofeedback. (6) Outcomes were evaluated according to questionnaires and the more objective pad test. There were no significant differences among the 3 groups.

In summary, the available data are insufficient to alter the policy statements.

References reviewed included:

- Goode PS, Burgio KL, Locher JL et al. Effect of behavioral training with or without pelvic floor electrical stimulation on stress incontinence in women: a randomized controlled trial. *JAMA* 2003;290(3):345-52.
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- Fujishiro T, Takahashi S, Enomoto H et al. Magnetic stimulation of the sacral roots for the treatment of urinary frequency and urge incontinence: an investigational study and placebo controlled trial. *J Urol* 2002;168(3):1036-9.

²² Based on 2005 Blue Cross and Blue Shield Association National Policy 1.01.17 updated 3/05. In January 2005, a review of the literature published since the 2000 TEC assessment identified few new reports that met study selection criteria and those identified do not change its conclusions. The national policy statement is unchanged and the policy is updated with additional references.

Wang and colleagues compared the outcomes of a 12-week program of pelvic floor muscle training, biofeedback-assisted pelvic floor muscle training, and electrical stimulation in a randomized study of in a group of 103 women with "over active bladder," primarily due to urge incontinence. (6) The biofeedback consisted of an intravaginal electromyogram probe, while an intravaginal electrode provided the electrical stimulation. Treatment outcomes included results of voiding diaries and quality of life measures, and urodynamic measures. The authors report that both the biofeedback and electrical stimulation groups reported an increased incidence of resolution or improvement of incontinence, but do not describe how this outcome was assessed. There were significant changes in some domains of the quality of life questionnaires in the biofeedback and electrical stimulation group, and the improvement in overall quality of life score was significantly better for the electrical stimulation compared to the pelvic floor exercise group. There were no significant differences in the voiding diary scores, but the authors rejected this outcome due to missing data in the diaries. Biofeedback was associated with the greatest improvement in muscle strengthening, but as noted above, muscle strength is not considered a key clinical outcome. Pad testing, the most objective outcome was not performed.

Yokoyama and colleagues reported on the comparative effects of electromagnetic pelvic floor stimulation compared to electrical stimulation and pelvic floor exercises in a group of 36 patients (12 in each group) with post-prostatectomy urinary incontinence. (15) The primary outcome was pad weight testing for up to 6 months after the 1-month treatment period. While the outcomes were similar after 6 months in all groups, at 1 month there was a significant improvement in the pad weight in the electromagnetic stimulation group compared to the control group. The promising short-term results in this small study require confirmation in larger studies.

In summary, the available data are insufficient to alter the policy statements. References reviewed included:

- 6) Wang AC, Wang YY, Chen MC. Single-blind, randomized trial of pelvic floor muscle training, biofeedback-assisted pelvic floor muscle training, and electrical stimulation in the management of overactive bladder. *Urology* 2004; 63(1): 61-6.
- 15) Yokoyama T, Nishiguchi J, Watanabe T et al. Comparative study of effects of extracorporeal magnetic innervation versus electrical stimulation for urinary incontinence after radical prostatectomy. *Urology* 2004; 63:264-67.

²³ Based upon the 2003 Blue Cross Blue Shield Association National policy 2.01.64. The National policy notes that the review of biofeedback for adults and children point out several methodological problems in the medical literature:

- Lack of uniform criteria for patient inclusion. Some studies include only chronic constipation patients, some only encopresis, and some constipation with encopresis. Studies will often fail to specify the characteristics of the population and the subgroups with different symptoms and diseases. Additionally, patients with weak pelvic floor muscles and normal rectal sensation may only need strength training and patients with normal pelvic floor muscle strength and poor rectal sensation may only need sensory or coordination training. Most studies do not identify and report the cause of incontinence and do not conduct analysis on patient subgroups
- Lack of standardized criteria for assessing outcome. Studies report cure rates and improvement rates but the outcomes and methods underlying their measurement varies across studies. The criteria for success has ranged arbitrarily from 25% to 90% reduction in episodes across studies.
- Diversity among treatment protocols. In their review of 34 studies, Norton and Kamm noted that no two studies have described exactly the same treatment as biofeedback
- Lack of randomized controlled trials. Most studies are uncontrolled observational studies of patients who undergo biofeedback treatment. Non-randomized controlled trials are subject to selection bias when patients chose which intervention group they will join.
- Small sample size and lack of statistical power. Small samples limits detection of small-to-moderate effect sizes and eliminates the opportunity for separate subgroup analysis.
- Short follow-up period. Outcomes for most studies are end of treatment or 6 months, studies rarely follow-up for 2 or more years.
- Lack of validated outcome measures. Diary, questionnaire, and interview methods are used to assess patient symptoms; the field has not conducted reliability and validity psychometric studies to standardize their operational definitions and methodological procedures.
- Nonspecific treatment effects. Biofeedback treatment is often performed concurrent with adjunctive therapy, including use of medication, diet modification, home instruction, and a home exercise program. In addition, critical factors to success may have more to do with contributions by therapist attention, psychological support, social and psychological counseling for anxiety and confidence, patient education, dietary assessment and advice, medication and lifestyle (e.g., pelvic floor muscle or sphincter exercise) changes, and patient motivation than the biofeedback.

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²⁴ Based upon the 2005 Blue Cross Blue Shield Association National policy 2.01.64 issued 3/05. A literature search was performed for the period of 2003 through November of 2004. No additional studies were identified that would prompt reconsideration of the policy statement; therefore the policy is unchanged.

Norton and colleagues reported on the results of a trial that randomized 171 patients with fecal incontinence to 1 of 4 groups: standard care (advice), advice plus instruction on sphincter exercises, hospital-based computer-assisted sphincter pressure biofeedback, and hospital biofeedback plus the use of a home EMG biofeedback device. (25) Outcomes included diary reports of incontinence, quality of life, and anal manometry measurements. The authors reported that biofeedback yielded no greater benefit than standard care. Solomon and colleagues reported on the results of a trial that randomized 120 with mild to moderate fecal incontinence to 1 of 3 groups: biofeedback with anal manometry, biofeedback with transanal ultrasound, or pelvic floor exercises with feedback from digital examination alone. (26) There were no significant differences in outcomes among the treatment groups; all reported modest improvements. Finally, Mahony and colleagues conducted a randomized trial in patients with postpartum fecal incontinence that compared the effects of intra-anal EMG biofeedback with or without additional treatment with intra-anal electrical stimulation. (27) This trial is not relevant to this policy since there was no placebo-controlled group.

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2006 Update: Based upon 2006 BCBSA National Policy 2.01.64 issued 7/06.

A literature review of the peer-reviewed literature on MEDLINE for the period of November 2004 through May 2005 identified no new clinical trial publications to alter the conclusions above. In a randomized controlled trial of only 23 female patients, Ilnyckyj and colleagues found no evidence biofeedback with education improved fecal continence over pelvic exercises with education. (28) In addition, a Cochrane review found no evidence that biofeedback training improved fecal continence in children over conventional treatment. (29) Therefore, the policy statement is unchanged.

Additional references reviewed:

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- 29) Brazzelli M, Griffiths P. Behavioural and cognitive interventions with or without other treatments for the management of faecal incontinence in children. *Cochrane Database Syst Rev* 2006 19; (2):CD002240.

²⁵ Based upon the 2006 Blue Cross Blue Shield Association National policy 7.01.69.

2005 Update: A literature search performed for the period of 2004 through March 2005 did not identify any additional published literature that would prompt reconsideration of the policy statement, which remains unchanged.

2006 Update: A literature review was conducted in May 2006. Findings from that review did not result in a change in any of the policy statements. A review article (17) again found substantial improvement for use of spinal cord stimulation in treating urinary urge incontinence, with about 80% of patients achieving continence or at least a 50% improvement in incontinence symptoms. This review also noted a re-operation rate of 33% of implanted cases; with pain and infection being the two most frequent causes. The authors also noted that over time technical changes have been associated with decreased complication rates. A small (27 patients) randomized trial of sacral nerve stimulation reported decreased episodes of fecal incontinence and improved quality of life. (18) However, additional studies are needed to confirm these results and also to better define patient selection criteria.

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3. TEC Assessments 2000; Tab 7.
4. Maher CF, Carey MP, Dwyer PL et al. Percutaneous sacral nerve root neuromodulation for intractable interstitial cystitis. *J Urol* 2001; 165(3):884-6.
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12. Matzel KE, Kamm MA, Stosser M et al. Sacral spinal nerve stimulation for faecal incontinence: multicentre study. *Lancet* 2004; 363(9417):1270-6.

13. Kenefick NJ, Nicholls RJ, Cohen RG et al. Permanent sacral nerve stimulation for treatment of idiopathic constipation. *Br J Surg* 2002; 89(7):882-8.
14. Malouf AJ, Wiesel PH, Nicholls T et al. Short-term effects of sacral nerve stimulation for idiopathic slow transit constipation. *World J Surg* 2002; 26(2):166-70.
15. Siegel S, Paszkiewicz E, Kirkpatrick C et al. Sacral nerve stimulation in patient with chronic intractable pelvic pain. *J Urol* 2001; 166(5):1742-5.
16. Medicare Coverage Policy. Sacral Nerve Stimulation for Urge Urinary Incontinence: Decision Memorandum (#CAG-00058N). June 29, 2001. Available online at <http://cms.hhs.gov/coverage/8b3-v.asp>.
17. Brazzelli M, Murray A, Fraser C. Efficacy and safety of sacral nerve stimulation for urinary urge incontinence: a systematic review. *J Urol* 2006; 175(3 pt 1):835-41.
18. Leroi AM, Parc Y, Lehur PA et al. Efficacy of sacral nerve stimulation for fecal incontinence: results of a multicenter double-blind crossover study. *Ann Surg* 2005; 242(5):662-9.

BCBSMA Medically necessary ICD-9 CM diagnoses for coverage of sacral nerve stimulation include:

- 788.20-retention of urine, unspecified
- 788.21-incomplete bladder emptying
- 788.31-urge incontinence
- 788.41-urinary frequency

²⁶ Based on Blue Cross Blue Shield National Policy 7.01.19 issued 4/05.

Periurethral bulking agents are recognized as treatment options for both men and women with stress incontinence (1-3). The 1996 Clinical Practice Guidelines for Urinary Continence in Adults, developed by the Agency for Health Care Policy and Research (AHCPR) concluded that periurethral collagen is curative in 32% of men and 62% of women. (4) Success may be maximized in men by assessing outcome after 4 injections, and by focusing treatment on those with milder degrees of incontinence. Carbon-coated beads (Durasphere) are a recently FDA-approved alternative to cross-linked collagen. They are designed to provide a more durable effect. A double-blind randomized study comparing the Durasphere to Contigen was reported to the FDA as part of the FDA-approval process. (5) At the end of the 12-month study period, the 2 devices reported equal effectiveness. There was also no difference in the number of treatments between the 2 groups, although the trial length of 12 months might not have been long enough to assess comparative durability. Results from this study were later published by Lightner and colleagues in 2001. (6) The copolymer implant (Uryx) received FDA approval based on a study that randomized 237 women with stress urinary incontinence to undergo periurethral bulking with Uryx or to a "currently marketed absorbable bulking agent." (7) The effectiveness at 12 months was similar in the 2 groups. For example, 18.4% and 48.7% of those receiving Uryx reported that they were either dry or had improved by 1 grade respectively, compared to 16.5% and 53.2% in the control group. A repeat injection was necessary in 75% of these patients to achieve satisfactory results.

Autologous fat and autologous ear chondrocytes are other materials that have been used as bulking agents but have not demonstrated sustained effectiveness comparable to cross-linked collagen or carbon-coated beads. Autologous substances do not require FDA approval. In a randomized, double-blind clinical trial of 56 female patients comparing periurethral injections of autologous fat (treatment group) to saline (placebo group), Lee and colleagues found periurethral fat injections did not appear to be more efficacious than placebo for treating stress incontinence. (8) At 3 months, only 6 of 27 patients (22.2%) in the treatment group and 6 of 29 (20.7%) in the placebo group were cured or improved. In addition, 1 death occurred as a result of a pulmonary fat embolism.

In another clinical trial of 32 female patients, Bent and colleagues reported 50% of patients remained dry for 12 months after receiving a single outpatient injection of harvested autologous auricular cartilage. (9) While autologous substances have a nonimmunogenic advantage, their use may be limited by resorption and fibrous replacement along with local discomfort associated with harvesting procedures. Further study of the use of autologous ear chondrocytes is also warranted.

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Medically necessary ICD-9 CM diagnoses codes for coverage of periurethral bulking agents for the treatment of incontinence are:

599.82-Intrinsic (urethral sphincter deficiency (ISD)

625.6-Stress incontinence, female

788.32- Urinary incontinence, male

²⁷Based on Blue Cross Blue Shield National policy 7.01.102 issued 6/27/05.

This is a new BCBSA policy stating periureteral bulking agents are considered investigational as a treatment of vesicoureteral reflux. Treatment of vesicoureteral reflux is based on the following assumptions:

- 1. VUR predisposes patients to URI
- 2. VUR predisposes patients to pyelonephritis
- 3. VUR predisposes to reflux nephropathy and renal scarring, potentially leading to morbidities related renal disease (i.e., hypertension, end stage disease).

Critical reviews of the natural history and treatment of VUR point out that these 3 assumptions, entrenched in pediatric practice, have never been proven. (4, 5) In 1997, the American Urological Association (AUA) published practice guidelines for the treatment of childhood VUR. These guidelines included literature published until 1994. (6,7) This review noted that there was little information regarding health outcomes related to reflux, for example the extent to which reflux increases the risk of renal scarring related to UTIs. These gaps in the understanding of the natural history and health outcomes of VUR underscore the importance of including final health outcomes (not just resolution of reflux itself) in studies of the treatment of VUR. Indeed, the AUA guidelines noted that only a few recommendations could be derived purely from scientific evidence of a beneficial effect on health outcomes, therefore, the guidelines were primarily based on expert opinion.

A 2004 Cochrane review focused on treatment of primary VUR. (1) This review analyzed the published randomized studies of surgery (including open surgery or endoscopic use of bulking agents), antibiotic prophylaxis of any duration and non-invasive techniques, such as bladder training. Outcome measures included final health outcomes, such as incidence of UTI, renal parenchymal abnormalities, development of hypertension, or renal function impairment. Correction of VUR and obstruction following VUR correction were also evaluated. Eleven randomized controlled trials were identified, 2 of which involved Deflux. (These 2 trials are reviewed in greater detail below.) Overall, the authors concluded that no significant differences in the risk for UTI or renal parenchymal injury were found in a meta-analysis of 7 trials with 847 evaluable patients combining antibiotic prophylaxis with combined surgery and antibiotics. This finding challenges the assumptions underlying the treatment of VUR, since one would expect a reduction in UTI if the hypothesis is correct that VUR is a modifiable risk factor for UTI and renal parenchymal damage. No differences between treatment groups were demonstrated for the endpoints of hypertension and chronic renal failure, but the trials were not powered to detect these endpoints and follow-up time was too short. Furthermore, data from available randomized trials did not provide evidence as to whether the current practice of diagnosing and treating children with VUR confers important health benefits since no adequately powered trials have included a no treatment arm. The only positive finding from the meta-analysis was a reduction in the incidence of febrile UTI in children surgically treated; however, the clinical significance of this finding is uncertain. For example, if one assumes a relatively high baseline 20% risk of a UTI, about 9 children would need to be treated with combined reimplantation surgery and antibiotics compared with antibiotics alone to prevent 1 febrile UTI during the ensuing 5 years.

Randomized Studies of Dextranomer/Hyaluronic Acid Copolymer (Deflux)

Capozza and colleagues reported on the results of a study of 61 children with VUR (grades II to IV) who were randomized to receive an endoscopic subureteral implantation (n=40) of Deflux or 12 months of antibiotic prophylaxis (n=21). (8) The 2001 FDA approval of Deflux was also based in part on this study. Entry criteria included grades II to IV reflux present for at least 6 months. The antibiotic therapy was not specified and presumably was variable. It was not reported whether patients had been receiving antibiotic therapy during the preceding 6 months and experienced breakthrough UTIs or were noncompliant, or showed no evidence of spontaneous resolution of VUR. Therefore it is unknown whether the Deflux treatment was primarily considered an alternative to medical therapy or to surgical therapy. In part due to the small numbers in the antibiotic control group, the distribution of the different grades of VUR were different in the 2 groups. Outcomes included improvement in reflux grade and measures of renal function; incidence of UTIs was not reported. The only significant outcome reported was the improvement in reflux grade, with 69% of those in the Deflux group reporting a reflux grade of ≤ 1, compared to only 38% in the antibiotic group. However, these results are not surprising, since antibiotic therapy in and of itself is not intended to improve reflux grade, but simply to sterilize the urine while awaiting the spontaneous resolution of VUR. Therefore, the only conclusion is that Deflux results in a higher incidence of VUR resolution compared to spontaneous resolution.

The second identified randomized study was reported by Oswald and colleagues, which randomized 72 children with VUR to receive either Deflux or Macroplastique in addition to antibiotic prophylaxis. (9) Entry criteria included Grades II to IV reflux. Since all patients continued to receive antibiotic therapy, presumably the bulking procedure was primarily considered an alternative to surgical reimplantation of ureters. However, the patient selection criteria do not indicate whether patients had failed prior antibiotic therapy or had unresolved VUR. Correction of underlying VUR was similar in the 2 groups.

There were no randomized studies comparing bulking procedures with surgical reimplantation. The Cochrane review states that bulking agents offer an alternative method of correcting VUR, although the rates of correction are lower than those reported with surgical reimplantation techniques. However, the Cochrane review also points out that the benefit of any type of correction of VUR is unproven at this point.

Additional Studies

Since the 2004 Cochrane report, no additional randomized studies have been reported. Additional case series of bulking agents including Deflux have been published that continue to report success rates of elimination of reflux in the 70% range, although the rates are higher in those with low-grade reflux and lower in those with high-grade reflux. (10,11) The fact that these case series include patients with Grades I and II reflux, typically treated with prophylactic antibiotics, and patients with Grades III and IV reflux, for whom surgery might be considered an initial therapy, suggests that bulking agents continue to be considered an alternative to either medical or surgical therapy. Many of the reports of the use of bulking agents are published in international journals, and it may be that this treatment option has been integrated into clinical practice primarily outside the United States.

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²⁸ Based on Blue Cross Blue Shield National Policy 1.01.17 issued 3/06. This policy was updated with literature review without change in policy statements specific to electrical and magnetic pelvic floor stimulation as a treatment of urinary incontinence. One additional reference was added. Amaro and colleagues reported on the results of a randomized study of pelvic floor stimulation in 40 women with mixed urinary incontinence. There was no significant difference in outcomes between the active and sham treatment groups.

Additional reference:

- 7) Amaro JL, Gameiro MO, Padovani CR. Effect of intravaginal electrical stimulation on pelvic floor muscle strength. *Int Urogynecol J Pelvic Floor Dysfunct* 2005; 16(5):355-8.

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