



BlueCross BlueShield
of Alabama

Name of Policy:

Urodynamic Testing to Evaluate Urinary Incontinence

Policy #: 315
Category: Medical

Latest Review Date: September 2011
Policy Grade: **Active Policy but no longer scheduled for regular literature reviews and updates.**

Background/Definitions:

As a general rule, benefits are payable under Blue Cross and Blue Shield of Alabama health plans only in cases of medical necessity and only if services or supplies are not investigational, provided the customer group contracts have such coverage.

The following Association Technology Evaluation Criteria must be met for a service/supply to be considered for coverage:

- 1. The technology must have final approval from the appropriate government regulatory bodies;*
- 2. The scientific evidence must permit conclusions concerning the effect of the technology on health outcomes;*
- 3. The technology must improve the net health outcome;*
- 4. The technology must be as beneficial as any established alternatives;*
- 5. The improvement must be attainable outside the investigational setting.*

Medical Necessity means that health care services (e.g., procedures, treatments, supplies, devices, equipment, facilities or drugs) that a physician, exercising prudent clinical judgment, would provide to a patient for the purpose of preventing, evaluating, diagnosing or treating an illness, injury or disease or its symptoms, and that are:

- 1. In accordance with generally accepted standards of medical practice; and*
- 2. Clinically appropriate in terms of type, frequency, extent, site and duration and considered effective for the patient's illness, injury or disease; and*
- 3. Not primarily for the convenience of the patient, physician or other health care provider; and*
- 4. Not more costly than an alternative service or sequence of services at least as likely to produce equivalent therapeutic or diagnostic results as to the diagnosis or treatment of that patient's illness, injury or disease.*

Description of Procedure or Service:

Urinary incontinence affects up to 70% of community-dwelling women and up to 50% of nursing home residents. Prevalence increases gradually during young adulthood, peaks broadly around middle age, and then steadily increases in the elderly. In up to 75% of ambulatory women with incontinence, urodynamic stress incontinence is the main condition. Detrusor overactivity accounts for up to 33% of incontinence cases, with the remainder being mixed forms. Most women with incontinence do not seek medical help.

Urodynamic testing refers to a group of tests used to assess function of the urinary tract by measuring various aspects of urine storage and evacuation. Some types of urodynamic testing include:

- Cystometry measures bladder pressure during bladder filling. It is used to assess detrusor activity and bladder sensation, capacity, and compliance. Cystometry can be simple and office based or it can be multichannel, including measurement of intra-abdominal, bladder, and detrusor (bladder minus intra-abdominal) pressures.
- Uroflowmetry measures urine volume voided over time. It can be done with or without a pressure-flow study.
- Pressure flow study measures both bladder pressure and urinary flow. It determines the mechanism of abnormal voiding revealed by a low flow rate on uroflowmetry.
- Urethral pressure profile measures the intraluminal pressure along the urethra with the bladder at rest.
- Leak point pressure refers to the amount of abdominal pressure required to overcome urethral resistance and produce urine leakage when the patient is not trying to void. The pressure can be produced by Valsalva or cough.
- Post-void residual volume measurement is made by straight catheterization or by bladder ultrasound. A high volume on repeat determinations indicates outlet obstruction or poor detrusor contractility.
- Video urodynamics is similar to conventional cystometry, but with the addition of a radio-opaque filling medium, video recorder, and x-ray equipment. Most authorities think it is seldom indicated.

Policy:

Urodynamic testing in the evaluation of women with urinary incontinence **meets** Blue Cross and Blue Shield of Alabama's medical criteria for coverage when any of the following indications are documented:

1. The diagnosis with respect to the type of urinary incontinence is uncertain, after the initial history and physical examination.
2. The patient's symptoms do not correlate with the objective physical findings.
3. The patient has mixed symptoms (stress and urge urinary incontinence).
4. The patient fails to improve with treatment or has failure of prior incontinence procedures.
5. The patient is being considered for surgical intervention and has a complicated diagnostic situation and is at high surgical risk.

6. The patient has a history of extensive pelvic surgeries, prior radiation therapy to the pelvis, or has neurologic abnormalities.
7. The patient has symptomatic pelvic organ prolapse (Grade III or higher).

Urodynamic testing in the evaluation of men **meets** Blue Cross and Blue Shield of Alabama's medical criteria for coverage when the following indications are documented:

1. Benign prostatic hypertrophy (BPH) – uroflowmetry only.
2. Pressure flow studies for the evaluation of urinary symptoms in men with maximum flow rates above 10ml./sec. with abnormal presentations .
3. For the evaluation of urinary symptoms in men who have failed prior invasive therapy for the treatment of BPH.
4. The patient has a history of extensive pelvic surgeries, prior radiation therapy to the pelvis, or has neurological abnormalities.

Benefit/Network Applications:

For these studies to be covered by Blue Cross Blue Shield of Alabama, urodynamic testing and the interpretation of the tests must be done in the office, clinic, or facility of a Blue Cross Blue Shield of Alabama participating provider and, if sent elsewhere for interpretation, be interpreted by a participating provider of Blue Cross Blue Shield of Alabama.

Blue Cross and Blue Shield of Alabama does not approve or deny procedures, services, testing, or equipment for our members. Our decisions concern coverage only. The decision of whether or not to have a certain test, treatment or procedure is one made between the physician and his/her patient. Blue Cross and Blue Shield of Alabama administers benefits based on the members' contract and corporate medical policies. Physicians should always exercise their best medical judgment in providing the care they feel is most appropriate for their patients. Needed care should not be delayed or refused because of a coverage determination.

Key Points:

The purpose of urodynamic testing is to aid in understanding physiologic mechanisms of lower urinary tract dysfunction, thereby improving the accuracy of diagnosis and facilitating targeted treatment.

There are some pitfalls in urodynamic testing that limit its value. These include lack of standardization of technical details, such as patient position, type of pressure sensor, and filling rate. These variables can affect results. Also, the artificial situation of the urodynamic lab may produce non-physiologic results. There may also be inconsistent reproducibility of test results in the same patient. There is a wide range of physiologic values in normal, asymptomatic patients. The absence of a specific abnormality during urodynamic testing does not exclude its existence, and not all abnormalities found during urodynamics are clinically significant. There are also variations in the qualifications and experience of the testers. There is controversy over the choice of which test to do (e.g., non-invasive flow, filling cystometrogram, pressure-flow studies) and when they should be repeated. These criteria influence the plausibility and validity

of the study results. Thus, an urodynamic test is not definitive and must be placed in the context of the entire evaluation.

The indications for urodynamic testing remain controversial. Current consensus statements and practice recommendations recommend conservative treatment prior to any urodynamic tests. A consensus on the indications for preoperative urodynamic studies in the evaluation of SUI is lacking. There are some situations in which testing may be useful. Below, the absolute indications for urodynamic testing from three different societies are summarized.

The Agency for Health Care Policy and Research recommends that urodynamic testing be done in these types of patients: surgical intervention is planned in a high surgical risk patient, uncertain diagnosis, symptomatic pelvic-organ prolapse, neurologic abnormalities, prior incontinence procedures, or radical pelvic surgery.

The following are the grade descriptions for pelvic organ prolapse:

- Grade I—halfway to the hymen
- Grade II—at the hymen
- Grade III—halfway out of the hymen
- Grade IV—total prolapse

The American College of Obstetrics and Gynecology (ACOG) recommends that urodynamic testing be done in patients with these conditions: mixed symptoms (stress and urge urinary incontinence), failure of prior incontinence procedures, to exclude detrusor overactivity, to identify potential risk factors for surgical failure, and to determine voiding mechanism.

The International Consultation on Incontinence recommends that urodynamic testing be done in patients with complicated cases of urinary incontinence, uncertain pathophysiology, or neurogenic voiding dysfunction.

The ACOG also specifically addressed the issue of urodynamic testing before surgery. They stated that these types of patients may not need urodynamic testing prior to surgery: non-pregnant women who lose urine only with physical exertion and have normal voiding habits (i.e., less than 8 voiding episodes per day and 2 per night); no associated neurologic or physical findings; no history of anti-incontinence or radical pelvic surgery; a hypermobile urethra, pliable vaginal wall, and adequate vaginal capacity on physical exam; and a normal post-void residual volume.

In summary, the indications for urodynamic testing are still heavily debated. They should be performed to address a specific question and should attempt to reproduce the patient's symptoms. The potential limitations of the test should be understood and acknowledged by the physician who interprets the results. The study should not be read in isolation, but should be integrated into the overall clinical picture.

Male Incontinence

Urinary incontinence may also be seen in men. Detrusor overactivity and outlet obstruction are the most common causes of urinary incontinence in older men. Detrusor overactivity occurs in

approximately 2/3 of men with obstruction, resulting in urgency and, less frequently, urge incontinence. Outlet obstruction may be a result of benign prostatic hyperplasia, prostate cancer, or urethral stricture. Most obstructed men, however, do not have urinary incontinence. Incontinence associated with obstruction often presents as post-void dribbling. One cause of stress incontinence in men is prostate surgery.

Benign prostatic hyperplasia (BPH) is a common disorder that is more frequent in men older than age 50 years. The clinical manifestations are lower urinary tract symptoms that include increased frequency of urination, nocturia, hesitancy, urgency, and weak urinary stream. The evaluation for BPH includes a history, physical exam, urinalysis, and serum creatinine. There are several other tests that may be performed as part of the evaluation of men with BPH, but the American Urological Association (AUA) considers them optional. These tests include the serum prostate specific antigen (PSA), maximal urinary flow rate, and post-void residual urine volume. Although these tests are optional, they are useful in most men. Another urodynamic test, the pressure flow study, is usually reserved for men with urinary symptoms and maximal flow rates above 15 mL/sec and those in whom the clinical manifestations are atypical and there is reason to suspect some problem other than or in addition to BPH.

The European Association of Urology (EAU) issued guidelines in 2004 in the assessment, therapy, and follow-up of men with lower urinary tract symptoms suggestive of benign prostatic obstruction (BPO). They recommended these tests for the initial assessment: medical history, physical examination including digital-rectal examination, International Prostate Symptom Score, urinalysis, serum creatinine and prostate specific antigen measurement, uroflowmetry and post-void residual volume. All other tests are optional or not recommended.

The Canadian Urological Association (CUA) issued guidelines in 2005 for the management of lower urinary tract symptoms in men with benign prostatic hyperplasia (BPH). They stated that the mandatory evaluation should include history, physical examination and urinalysis, while a symptom inventory and PSA in selected patients are recommended. They stated that serum creatinine, uroflow, voiding diary, post-void residual, and sexual function questionnaire are optional.

Parkinson's disease (PD) is a chronic, progressive neurodegenerative disorder that is characterized by four cardinal signs: rest tremor, rigidity, bradykinesia, and gait disturbance. One complication of PD is urinary incontinence. Testing of autonomic function, including urodynamic testing, urethral or anal sphincter EMG, or sympathetic skin responses, has been examined as a potential tool for differentiating PD from other parkinsonian syndromes, especially multiple system atrophy (MSA). These tests, however, are generally not widely available, and there is insufficient evidence to recommend their routine use as diagnostic tests for PD.

January 2010 Update:

Lemack et al proposed that urodynamic studies performed preoperatively could be used as a means of identifying patients at risk for voiding dysfunction after surgery for stress urinary incontinence. Data were analyzed from preoperative, standardized urodynamic studies performed on 655 female participants in the Stress Incontinence Treatment Efficacy Trial, in

which women with stress urinary incontinence were randomized to undergo pubovaginal sling surgery or Burch colposuspension. Of the participants, 57 developed voiding dysfunction, including 8 in the Burch colposuspension and 49 in the pubovaginal sling groups. No preoperative urodynamic study findings were associated with an increased risk of voiding dysfunction in any group. Voiding pressures and degree of abdominal straining were not associated with postoperative voiding dysfunction. The authors concluded that preoperative urodynamic studies did not predict postoperative voiding dysfunction or the risk of surgical revision in the pubovaginal sling groups. The findings were limited by the stringent exclusion criteria and studying a group believed to be at greater risk for voiding dysfunction could alter these findings. Additional analysis using subjective measures to define voiding dysfunction is warranted for further determine the ability of urodynamic studies to stratify the risk of postoperative voiding dysfunction, which appears to be limited in the current study.

No studies were identified that would alter the coverage statement of the policy.

2011 Update

There are some ongoing trials that look at the value of preoperative urodynamic testing and whether it affects treatment decision and treatment outcomes. Two of these studies are summarized below.

Nager et al (2009) reported on the design of the value of urodynamic evaluation (VALUE) trial: a non inferiority randomized trial of preoperative urodynamic investigations. Urodynamic studies (UDS) are routinely obtained prior to surgery for stress urinary incontinence (SUI) despite a lack of evidence that UDS information has an actual impact on outcome. The primary aim of this non-inferiority randomized clinical trial is to determine whether women with symptomatic, uncomplicated SUI who undergo only a basic office evaluation (BOE) prior to SUI surgery (No UDS arm) have non-inferior treatment outcomes compared to women who have BOE and UDS (UDS arm). Secondary aims are: to determine how often physicians use preoperative UDS results to alter clinical and surgical decision-making, to compare the amount of improvement in incontinence outcomes, and to determine the incremental cost and utility of performing UDS compared with not performing UDS. The primary outcome will be measured at 12 months using responses to the Urogenital Distress Inventory and the Patient Global Index-Improvement. This trial is on-going.

Murdoch et al (2010) reported on the INVESTIGATE-1 (INVasive Evaluation before surgical treatment gives added therapeutic effect?) trial. Urinary incontinence is an important health problem to the individual sufferer and to health services. Stress and stress predominant mixed urinary incontinence are increasingly managed by surgery due to advances in surgical techniques. Despite the lack of evidence for its clinical utility, most clinicians undertake invasive urodynamic testing (IUT) to confirm a functional diagnosis of urodynamic stress incontinence before offering surgery for this condition. IUT is expensive, embarrassing and uncomfortable for women and carries a small risk. Recent systematic reviews have confirmed the lack of high quality evidence of effectiveness. The aim of this pilot study is to test the feasibility of a future definitive randomized control trial that would address whether IUT alters treatment decisions and treatment outcome in women and would test its clinical and cost effectiveness. This trial is on-going.

There were no new studies identified that would alter the coverage statement of the policy.

Key Words:

Urodynamic testing, urinary stress incontinence

Approved by Governing Bodies:

Not applicable

Benefit Application:

Coverage is subject to member's specific benefits. Group specific policy will supersede this policy when applicable.

ITS: Home Policy provisions apply

FEP contracts: Special benefit consideration may apply. Refer to member's benefit plan.

Pre-certification requirements: Not applicable

Current Coding

CPT codes:

- 51725 Simple cystometrogram (CMG) (e.g., spinal manometer)
- 51726 Complex cystometrogram (i.e., calibrated electronic equipment)
- 51736 Simple uroflowmetry (UFR) (e.g., stop-watch flow rate, mechanical uroflowmeter)
- 51741 Complex uroflowmetry (e.g., calibrated electronic equipment)
- 51784 Electromyography studies (EMG) of anal or urethral sphincter, other than needle, any technique
- 51785 Needle electromyography studies (EMG) of anal or urethral sphincter, any technique
- 51792 Stimulus evoked response (e.g., measurement of bulbocavernosus reflex latency time)
- 51797 Intra abdominal voiding pressure (AP) (rectal, gastric, intraperitoneal) use 51797 in conjunction with 51795
- 51798 Measurement of post-voiding residual urine and/or bladder capacity by ultrasound, non-imaging

Effective for dates of service on or after January 1, 2010:

- 51727 Complex cystometrogram (i.e., calibrated electronic equipment); with urethral pressure profile studies (i.e., urethral closure pressure profile), and technique
- 51728 Complex cystometrogram (i.e., calibrated electronic equipment); with voiding pressure studies (i.e., bladder voiding pressure), any technique

- 51729** Complex cystometrogram (i.e., calibrated electronic equipment); with voiding pressure studies (i.e., bladder voiding pressure) and urethral pressure profile studies (i.e., urethral closure pressure profile), any technique
- 51797** Voiding pressure studies, intra-abdominal (i.e., rectal, gastric, intraperitoneal) (List separately in addition to code for primary procedure)

Previous Coding

- 51772** Urethral pressure profile studies (UPP) (urethral closure pressure profile) **(Code deleted effective January 1, 2010)**
- 51795** Voiding pressure studies (VP); bladder voiding pressure, any technique **(Code deleted effective January 1, 2010)**

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Policy History:

Medical Policy Group, October 2008 (4)

Medical Policy Administration Committee, November 2008

Available for comment November 6-December 19, 2008

Medical Policy Group, January 2010 (1)

Medical Policy Group, September 2011(3); Updated Key Points and References

Medical Policy Group, September 2012 (3): Effective September 14, 2012 this policy is no longer scheduled for regular literature reviews and updates.

This medical policy is not an authorization, certification, explanation of benefits, or a contract. Eligibility and benefits are determined on a case-by-case basis according to the terms of the member's plan in effect as of the date services are rendered. All medical policies are based on (i) research of current medical literature and (ii) review of common medical practices in the treatment and diagnosis of disease as of the date hereof. Physicians and other providers are solely responsible for all aspects of medical care and treatment, including the type, quality, and levels of care and treatment.

This policy is intended to be used for adjudication of claims (including pre-admission certification, pre-determinations, and pre-procedure review) in Blue Cross and Blue Shield's administration of plan contracts.