02.01.75 Artificial Urinary Sphincter

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Original Effective Date: September 2010

Review Date: September 2025

Revised: August 2023

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This Medical Policy document describes the status of medical technology at the time the document was developed. Since that time, new technology may have emerged, or new medical literature may have been published. This Medical Policy will be reviewed regularly and updated as scientific and medical literature becomes available; therefore, policies are subject to change without notice.

Related Policies:

- 02.01.73 Biofeedback as a Treatment of Urinary Incontinence
- 02.01.76 Periurethral Bulking Agents for the Treatment of Stress Urinary Incontinence
- 02.01.77 Periurethral Bulking Agents as a Treatment of Vesicoureteral Reflux
- 02.01.78 Percutaneous and Implantable Posterior Tibial Nerve Stimulation
- 02.01.79 Miscellaneous Investigational Therapies and Tests for the Treatment of Urinary Incontinence/Urinary Dysfunction

Summary

Description

The artificial urinary sphincter (AUS) is an externally controlled urethral occlusion device used to treat urinary incontinence due to reduced outlet resistance following prostate surgery.

Summary of Evidence

For individuals who have urinary incontinence (UI) due to intrinsic urethral sphincter deficiency (IUSD) following prostate surgery who receive an AUS, the evidence includes systematic reviews, a randomized controlled trial (RCT) and comparative and noncomparative observational studies. Relevant outcomes are symptoms, change in disease status, functional outcomes, quality of life, and treatment-related morbidity. After a mean follow-up of 2.7 to 5.4 years, pad use decreased, and dry rates ranged from 58% to 68%. Need for re-operative procedures occurred in 20% to 35% of individuals. The evidence is sufficient to determine that the technology results in an improvement in the net health outcome.

For individuals with other miscellaneous conditions who receive AUS to include but not limited to epispadias-exstrophy in whom bladder neck reconstruction has failed; XX individuals in whom behavioral or pharmacologic therapies, or other surgical options have failed; and children with intractable UI who are refractory to pharmacologic therapies or unsuitable for other types of operation who receive an AUS, the evidence includes noncomparative observational studies and a systematic review of these studies. No randomized controlled trials were identified. Relevant outcomes are symptoms, change in disease status, functional outcomes, quality of life, and treatment-related morbidity. The systematic review of 15 uncontrolled retrospective and prospective studies with a mean of 68 XX individuals per study reported a median continence rate of 79% and a revision rate of 15%. However, no conclusions could be drawn based on these findings as the quality of evidence as very low quality due to high risk of bias in all of the included studies as well as publication bias and “serious imprecision”. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

Additional Information

None

OBJECTIVE

The objective of this evidence review is to determine whether the use of the artificial urinary sphincter (AUS) improves the net health outcome in individuals who have urinary incontinence (UI) due to intrinsic urethral sphincter deficiency (IUSD) following prostate surgery or with epispadias-exstrophy in whom bladder neck reconstruction has failed; XX individuals in whom behavioral or pharmacologic therapies, or other surgical options have failed; and children with intractable UI who are refractory to pharmacologic therapies or unsuitable for other types of operation.

PRIOR APPROVAL

Not applicable.

POLICY

Medically Necessary

An artificial urinary sphincter (AUS) may be considered **medically necessary** in individuals who meet **all of the following**:

- Who have had prostate surgery (post-proctectomy) for the treatment of urinary incontinence (UI) due to intrinsic sphincter deficiency (ISD); **and**
- Symptoms of urinary incontinence (UI) have been refractory to at least 6 months of conservative therapy to include **one of the following**: bladder training, prompted voiding, or pelvic muscle exercise training and pharmacological therapies.

Investigational

The implantation of an artificial urinary sphincter (AUS) may be considered **investigational** when the above criteria have not been met and for all other indications because the evidence is insufficient to determine the technology results in an improvement in the net health outcomes.

POLICY GUIDELINES

The implantation of an artificial urinary sphincter (AUS) is not considered first-line treatment of refractory urinary incontinence (UI) in members following prostate surgery. Examples of first-line conservative therapy may include one or more of the following: behavioral therapy, pharmacologic treatments, and intermittent self-catheterization.

Coding

See the Codes table for details.

BACKGROUND

Artificial Urinary Sphincter (AUS)

The artificial urinary sphincter (AUS) is an externally controlled urethral occlusion device. The transfer of fluid within the device is controlled by a pressure-regulating balloon placed extra-peritoneally in the individual's pelvis or abdominal cavity and a control pump placed in a subcutaneous pocket in the scrotum. Squeezing of the pump allows fluid within the closed-loop system to be transferred from the cuff to the balloon. It takes a few minutes before the cuff re-inflates automatically to the preset level, allowing the urethra to remain open for voiding. The valve then automatically re-tightens several minutes later which closes the urethra, thereby enabling control of urine flow and continence to be achieved.

Potential candidates for AUS implantation should be evaluated preoperatively to exclude severe detrusor instability as well as to ensure adequate bladder stability and compliance prior to implantation of the AUS. Appropriate candidates for implantation of an AUS must have adequate motivation and sufficient manual dexterity to operate the device. Post-prostatectomy patients should wait 6 to 12 months and attempt behavioral and pharmacologic therapies first.

Regulatory Status

On 6/14/2001, the U.S. Food and Drug Administration approved the AMS Sphincter 800™ Urinary Control System (Boston Scientific Corp., P000053, product code EZY) for urinary incontinence due to reduced outlet resistance following prostate surgery.
https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpma/pma.cfm?ID=P000053

RATIONALE

This evidence review was created in September 2010 with searches of the PubMed database. The most recent literature update was performed through August 2025.

Evidence reviews assess the clinical evidence to determine whether the use of technology improves the net health outcome. Broadly defined, health outcomes are length of life, quality of life, and ability to function, including benefits and harms. Every clinical condition has specific outcomes that are important to patients and managing the course of that condition. Validated outcome measures are necessary to ascertain whether a condition improves or worsens; and whether the magnitude of that change is clinically significant. The net health outcome is a balance of benefits and harms.

To assess whether the evidence is sufficient to draw conclusions about the net health outcome of technology, 2 domains are examined: the relevance, and quality and credibility. To be relevant, studies must represent 1 or more intended clinical use of the technology in the intended population and compare an effective and appropriate alternative at a comparable intensity. For some conditions, the alternative will be supportive care or surveillance. The quality and credibility of the evidence depend on study design and conduct, minimizing bias and confounding that can generate incorrect findings. The randomized controlled trial (RCT) is preferred to assess efficacy; however, in some circumstances, nonrandomized studies may be adequate. RCTs are rarely large enough or long enough to capture less common adverse events and long-term effects. Other types of studies can be used for these purposes and to assess generalizability to broader clinical populations and settings of clinical practice.

Individuals with Urinary Incontinence (UI) due to Intrinsic Urethral Sphincter Deficiency (IUSD) following Prostate Surgery

Clinical Context and Therapy Purpose

The purpose of artificial urinary sphincter (AUS) use in individuals with urinary incontinence (UI) due to intrinsic urethral sphincter deficiency (IUSD) following prostate surgery is to provide a treatment option that is an alternative to or an improvement on existing therapies.

The following PICO was used to select literature to inform this review.

Populations

The relevant populations of interest are individuals with urinary incontinence (UI) due to intrinsic urethral sphincter deficiency (IUSD) following prostate surgery.

Interventions

The therapy being considered is AUS.

Comparators

The following treatment options are being considered as alternatives to AUS: Conservative treatments including, but not limited to behavioral modification, use of pads/incontinence briefs, penile compressive devices, and condom catheters.

Outcomes

The general outcomes of interest are reductions in symptoms (e.g., self-reported assessment of symptoms, decrease in the number of voids per day) and improved quality of life. Outcomes are measured following the 12-week treatment regimen.

Study Selection Criteria

Methodologically credible studies were selected using the following principles:

- To assess efficacy outcomes, comparative controlled prospective trials were sought, with a preference for RCTs;
- In the absence of such trials, comparative observational studies were sought, with a preference for prospective studies.
- To assess long-term outcomes and adverse events, single-arm studies that capture longer periods of follow-up and/or larger populations were sought.
- Studies with duplicative or overlapping populations were excluded.

Review of Evidence

Systematic Review

In a systematic review by Bomba et al (2019) that studied men with post-prostatectomy incontinence who were treated with artificial urinary sphincter (AUS) or an adjustable sling the authors identified seven studies with a total of 463 participants, 420 of whom had SUI following prostatectomy. In the studies, 313 received an AUS and 107 received an adjustable sling. There were no RCTs and no head-to-head comparisons of AUS and adjustable slings. The primary outcome of the review was decreased pad use. The analysis for this outcome included three studies on each intervention. Compared with no intervention, pad use decreased with either intervention and there was no statistically significant difference between interventions.

A systematic review by Li et al (2023) also found that AUS significantly reduced pad use and improved quality of life.

Observational Studies

Several observational studies have evaluated the use of artificial urinary sphincter (AUS) in male adults with refractory urinary incontinence due to intrinsic sphincter deficiency (ISD) following prostate surgery. A multicenter retrospective cohort study was published by Tutolo et. al. (2019) which included 892 cases of AUS implantation in men with non-neurogenic stress urinary incontinence (SUI) after prostate surgery who were followed for at least 1 year. The mean length of follow-up was 32 months (range 12 to 300 months). The primary outcome was the dry rate (DR), defined as not needing to use any pads. Data on pad use prior to surgery were available for 547 of the 892 individuals in the cohort (61%). All the 547 individuals used at least 1 pad per day prior to treatment, including 368 (67%) who used at least 5 pads. At follow-up, the DR was 58% for the cohort. Among individuals without previous incontinence surgery, 409 of 724 (57%) were dry at follow-up, and the DR was 48% in individuals with previous incontinence surgery (80 of 168). The overall complication rate was 28% (248 individuals) and consisted of erosion, infection, urethral atrophy and mechanical failure.

In 2019, Boswell et al evaluated the long-term survival and reintervention rates. The study included 1154 individuals who underwent AUS placement for SUI following radical prostatectomy or other prostate procedure. Individuals were followed for a mean of 5.4 years. The rate of secondary surgery (removal or revision) was 35% (404 of 1154). According to Kaplan-Meier survival analysis, estimates of rates of device survival were 72% at 5 years, 56% at 10 years, 41% at 15 years and 33% at 20 years.

In 2017 Sacomani et al reported on long-term outcomes in 121 consecutive individuals who underwent artificial urinary sphincter (AUS) implantation following prostatectomy. After a mean follow-up of 5.2 years, 106 men (88%) still had their AUS device and 82 of these (68%) reported being completely dry. Investigators have noted high complication rates, (for example, infection, erosion, mechanical failure, and device explantation) and need for reoperative procedures in up to 20% of implanted individuals. For these reasons, AUS is not considered a first-line therapy and is reserved for those who have not responded to conventional treatment options for at least 6 months following prostate surgery.

Section Summary: Individuals with Urinary Incontinence (UI) due to Intrinsic Urethral Sphincter Deficiency (IUSD) following Prostate Surgery

Based on the review of peer reviewed medical literature the artificial urinary sphincter (AUS) has been shown to be effective for urinary incontinence (UI) due to intrinsic urethral sphincter deficiency (IUSD) following prostate surgery. AUS is not considered a first-line therapy and is reserved for those who have not responded to conventional treatment options for at least 6 months following prostate surgery.

Other Miscellaneous Uses of Artificial Urinary Sphincter

Clinical Context and Therapy Purpose
The purpose of artificial urinary sphincter (AUS) use in individuals with epispadias-exstrophy in whom bladder neck reconstruction has failed; women in whom behavioral or pharmacologic therapies, or other surgical options have failed; and children with intractable UI who are refractory to pharmacologic therapies or unsuitable for other types of operation is to provide a treatment option that is an alternative to or an improvement on existing therapies.

The following PICO was used to select literature to inform this review.

Populations
The relevant population of interest include individuals with epispadias-exstrophy in whom bladder neck reconstruction has failed; women in whom behavioral or pharmacologic therapies, or other surgical options have failed; and children with intractable UI who are refractory to pharmacologic therapies or unsuitable for other types of operation.

Interventions
The therapy being considered is AUS.

Comparators
The following treatment options are being considered as alternatives to AUS: Conservative treatments including, but not limited to behavioral modification, use of pads/incontinence briefs and other surgical treatment options.

Outcomes
The general outcomes of interest are reductions in symptoms (e.g., self-reported assessment of symptoms, decrease in the number of voids per day) and improved quality of life. Outcomes are measured following the 12-week treatment regimen.

Study Selection Criteria
Methodologically credible studies were selected using the following principles:

- To assess efficacy outcomes, comparative controlled prospective trials were sought, with a preference for RCTs;
- In the absence of such trials, comparative observational studies were sought, with a preference for prospective studies.
- To assess long-term outcomes and adverse events, single-arm studies that capture longer periods of follow-up and/or larger populations were sought.
- Studies with duplicative or overlapping populations were excluded.

Review of Evidence

Systematic Review
In 2020, Barakat et al in a systematic review published on artificial urinary sphincter (AUS) for XX individuals with stress urinary incontinence (SUI) identified 15 uncontrolled retrospective and prospective studies with a mean of 68 individuals per study. The authors rated the quality of evidence as very low quality due to high risk of bias in all of the included studies as well as publication bias and “serious imprecision”. In a meta-analysis, the authors noted a high degree of heterogeneity in the post-operative

continence rate and found a median continence rate of 79%. They also found a revision rate of 15%. Despite the high rate of post-operative continence, the authors concluded that the low quality of evidence and small study population were insufficient to draw firm conclusions about the impact of AUS on the net health outcome in XX individuals.

Observational Study

Denormandie (2021) et al reported on an uncontrolled retrospective study on 45 women over 75 years old with stress urinary incontinence (SUI) due to intrinsic urethral sphincter deficiency (ISD) who had artificial urinary sphincter (AUS) implantation. During surgery, bladder dome injuries occurred in 9 (20%) of women and vaginal injuries occurred in 3 (6.7%) women. There were 26 early postoperative complications in 18 individuals (40%); all except 1 were minor complications. Median follow-up was 36 months. Five individuals died for reasons unrelated to the surgery and did not complete follow-up. Late postoperative complications occurred in 7 women (15.5%). At the final follow-up, 32 of the 45 individuals (71%) had their original AUS, 2 had explanted AUS, 9 had AUS revisions and 2 had AUS deactivations. In an intention-to-treat analysis, 31 of the 45 women (69%) had total continence at last follow-up.

Section Summary: Clinically Valid

To date, the evidence from well-designed studies is insufficient to form conclusions regarding the safety and efficacy of AUS for other subgroups, such as XX individuals and, children with intractable incontinence, and XY individuals who have not undergone prostate surgery. Further randomized controlled trials (RCTs) with long term follow-up are needed to determine the safety and efficacy.

SUPPLEMENTAL INFORMATION

The purpose of the following information is to provide reference material. Inclusion does not imply endorsement or alignment with the evidence review conclusions.

Practice Guidelines and Position Statements

Guidelines or position statements will be considered for inclusion in ‘Supplemental Information' if they were issued by, or jointly by, a US professional society, an international society with US representation, or National Institute for Health and Care Excellence (NICE). Priority will be given to guidelines that are informed by a systematic review, include strength of evidence ratings, and include a description of management of conflict of interest.

American Urological Association (AUA)/ Society of Genitourinary Reconstructive Surgeons (GURS)/ Society of Urodynamics, Female Pelvic Medicine & Urogenital Reconstruction (SUFU)

In 2019, the American Urological Association (AUA)/Society of Urodynamics, Female Pelvic Medicine & Urogenital Reconstruction (SUFU) published a guideline that was amended in 2024 on incontinence after prostate treatment (Sandhu, 2024). The guideline included the following statements on AUS:

- Clinicians should discuss the option of artificial urinary sphincter with patients who are experiencing mild to severe stress urinary incontinence after prostate treatment. (Strong Recommendation; Evidence Level: Grade B)
- Prior to implantation of artificial urinary sphincter, clinicians should ensure that patients have adequate physical and cognitive abilities to operate the device. (Clinical Principle)
- In patients who select artificial urinary sphincter, clinicians should preferentially utilize a single cuff perineal approach. (Moderate Recommendation; Evidence Level: Grade C)
- In patients with stress urinary incontinence after primary, adjuvant, or salvage radiotherapy who are seeking surgical management, clinicians should offer artificial urinary sphincter over male slings or adjustable balloons. (*Moderate Recommendation; Evidence Level: Grade C*)

- Clinicians may counsel patients regarding risk factors for artificial urinary sphincter erosion. (Conditional Recommendation; Evidence Level: Grade C)
- Clinicians should counsel patients that artificial urinary sphincter will likely lose effectiveness over time, and reoperations are common. (Strong Recommendation; Evidence Level: Grade B)
- In patients with persistent or recurrent stress urinary incontinence after sling, clinicians should recommend an artificial urinary sphincter. (*Moderate Recommendation; Evidence Level: Grade C*)
- In patients with persistent or recurrent stress urinary incontinence after artificial urinary sphincter, clinicians should discuss artificial urinary sphincter revision with the patient. (*Strong Recommendation; Evidence Level: Grade B*)
- In patients presenting with infection or erosion of an artificial urinary sphincter or sling, clinicians should perform explantation and reimplantation should be delayed. (*Clinical Principle*)
- After explanting an eroded device, clinicians may manage artificial urinary sphincter urethral cuff erosion intraoperatively with urethral catheter alone, in situ urethroplasty, or anastomotic urethroplasty. (*Expert Opinion*)
- In patients with stress urinary incontinence following urethral reconstructive surgery, clinicians may offer artificial urinary sphincter and counsel that complication rates are higher. (*Conditional Recommendation; Evidence Level:Grade C*)

Ongoing and Unpublished Clinical Trials

Some currently ongoing and unpublished trials that might influence this review can be located at clinicaltrials.gov.

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CODES

To report provider services, use appropriate CPT codes, HCPCS codes, Revenue codes, and/or ICD diagnosis codes.

Codes	Number	Description
CPT		
	53445	Insertion of inflatable urethral/bladder neck sphincter, including placement of pump, reservoir, and cuff
	53446	Removal of inflatable urethral/bladder neck sphincter, including pump, reservoir, and cuff
	53447	Removal and replacement of inflatable urethral/bladder neck sphincter including pump, reservoir, and cuff at the same operative session
	53449	Repair of inflatable urethral/bladder neck sphincter including pump, reservoir, and cuff
HCPCS		
	C1815	Prosthesis, urinary sphincter (implantable)

Codes	Number	Description
Type of Service	Surgery	
Place of Service	Inpatient/Outpatient	

POLICY HISTORY

Date	Reason	Action
September 2025	Annual Review	Policy Renewed
September 2024	Annual Review	Policy Renewed
August 2023	Annual Review	Policy Revised
July 2022	Interim Review	Policy Revised
June 2022	Annual Review	Policy Revised
April 2022	Interim Review	Policy Revised
June 2021	Annual Review	Policy Revised
June 2020	Annual Review	Policy Revised
June 2019	Annual Review	Policy Revised
June 2018	Annual Review	Policy Revised
June 2017	Annual Review	Policy Revised
July 2016	Annual Review	Policy Revised
July 2015	Annual Review	Policy Revised
August 2014	Annual Review	Policy Renewed
May 2014	Interim Review	Policy Revised
September 2013	Annual Review	Policy Revised
October 2012	Annual Review	Policy Renewed
October 2011	Annual Review	Policy Renewed

Date	Reason	Action
September 2010	Annual Review	Policy Renewed

New information or technology that would be relevant for Wellmark to consider when this policy is next reviewed may be submitted to:

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