Clinical Policy Title: Surgical and invasive treatments for overactive bladder syndrome

Clinical Policy Number: 13.03.02

Effective Date: April 1, 2015
Initial Review Date: January 14, 2015
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Next Review Date: March 2018

Related policies:
None.

ABOUT THIS POLICY: AmeriHealth Caritas Pennsylvania has developed clinical policies to assist with making coverage determinations. AmeriHealth Caritas Pennsylvania’s clinical policies are based on guidelines from established industry sources, such as the Centers for Medicare & Medicaid Services (CMS), state regulatory agencies, the American Medical Association (AMA), medical specialty professional societies, and peer-reviewed professional literature. These clinical policies along with other sources, such as plan benefits and state and federal laws and regulatory requirements, including any state- or plan-specific definition of “medically necessary,” and the specific facts of the particular situation are considered by AmeriHealth Caritas Pennsylvania when making coverage determinations. In the event of conflict between this clinical policy and plan benefits and/or state or federal laws and/or regulatory requirements, the plan benefits and/or state and federal laws and/or regulatory requirements shall control. AmeriHealth Caritas Pennsylvania’s clinical policies are for informational purposes only and not intended as medical advice or to direct treatment. Physicians and other health care providers are solely responsible for the treatment decisions for their patients. AmeriHealth Caritas Pennsylvania’s clinical policies are reflective of evidence-based medicine at the time of review. As medical science evolves, AmeriHealth Caritas Pennsylvania will update its clinical policies as necessary. AmeriHealth Caritas Pennsylvania’s clinical policies are not guarantees of payment.

Coverage policy

AmeriHealth Caritas Pennsylvania considers the use of the following surgical and invasive treatments for overactive bladder (OAB) syndrome to be clinically proven and, therefore, medically necessary when all of the following criteria are met:

I. Conservative therapy should be considered prior to the initiation of medical or surgical treatment of urinary incontinence (UI) for a trial of six months to 12 months. These include:
   a. Behavioral modifications, such as scheduled voiding, diet modification, fluid restriction when appropriate, smoking cessation, avoidance of caffeine, and bladder training.
   b. Pelvic floor muscle training (PFMT).

II. One of the following surgical indications is documented:
   a. Stress incontinence, demonstrated by physical examination or stress test (e.g., Marshall test cystography or urodynamic testing).
b. Confirmation of urethral sphincter hypermobility by physical examination, cystography, ultrasound, or cystoscopy.

c. Acceptable post void residual (PVR) test (as identified by the attending physician, as there is no universally accepted definition of a significant residual urine volume)

d. Absence of detrusor instability, urgency, or frequency, as primary etiologies, which may require urodynamic studies.

e. Absence of fistula, urethral ectopy, bladder calculi, urethral diverticula, or overflow incontinence etiology (unless well-treated stress incontinence, demonstrated by physical examination or stress test, such as the Marshall test, cystography, urodynamic testing).

f. Confirmation of urethral sphincter hypermobility, by physical examination, cystography, ultrasound or cystoscopy.

III. The following surgical and invasive procedures for OAB are clinically proven and medically necessary when criteria are met:

   a. Anterior colporrhaphy with bladder neck (Kelly-Kennedy) plication.

   b. Retropubic suspension (e.g., retropubic urethropexy or Burch procedure).

   c. Sling procedures (e.g., pubovaginal or suburethral sling; midurethral sling [transvaginal tapes (TVT), transobturator slings (TOT)]; bulbourethral sling).

IV. Artificial urinary sphincter implantation due to reduced outlet resistance (intrinsic sphincter deficiency) for males with severely symptomatic stress incontinence or following prostate surgery is considered medically necessary for:

   a. Members who are six or more months post-prostatectomy who have had no improvement in the severity of UI despite trials of behavioral and pharmacological therapies.

   b. Injection of periurethral bulking* (collagen, carbon-coated beads, or fat) as second-line therapy.

V. Periurethral bulking injections including Botox for women ineligible for surgery, are considered medically necessary when one or more criteria are met:

   a. The member has stress urinary incontinence (SUI) caused by intrinsic sphincter deficiency (ISD) that persists despite at least 12 consecutive months of conventional therapy (for example, pelvic floor exercises, behavioral modification, or pessary).

   b. Post-traumatic or post-surgical injury is present.

   c. Urethral hypermobility in females with abdominal leak point less than 100 cm H2O that persists despite at least 12 consecutive months of conventional therapy (for example, exercise or use of an anticholinergic medication).

   d. Stress urinary incontinence significantly limits activities of daily living.

   e. No other causes of stress urinary incontinence have been identified (e.g., urinary tract infection).
Members whose incontinence does not improve after three treatments with bulking agents are considered treatment failures and are not likely to respond to this therapy. In such cases, further treatment with bulking agents is not considered medically necessary.

VI. Sacral nerve stimulation (SNS) or sacral neuromodulation (SNM) (e.g., InterStim® Medtronic) is considered medically necessary when all of the following are present:

a. Patient has a diagnosis of urge incontinence, urgency frequency, or non-obstructive urinary retention.

b. Symptoms of incontinence have been present for at least 12 months and have resulted in significant disability, such as the limited ability to work or participate in activities outside of the home.

c. Incontinence is not related to a neurologic condition.

d. Previous behavioral and pharmacological therapies have been unsuccessful for at least six months.

e. A percutaneous stimulation test to determine candidacy for a permanent implantation has provided at least a 50 percent reduction in incontinence symptoms as documented in voiding diaries.

f. The member has experienced urge UI or symptoms of urge frequency for at least 12 months, and the condition has resulted in significant disability (the frequency and/or severity of symptoms are limiting the member's ability to participate in daily activities.

Limitations:

All other surgical interventions for the treatment of OAB syndrome are not medically necessary.

The following technologies for the treatment of OAB syndrome are considered experimental and investigational and, therefore, are not medically necessary:

- Sacral nerve stimulator for stress incontinence or urge incontinence due to a neurologic condition, such as detrusor hyperreflexia, multiple sclerosis, or spinal cord injury.
- Periurethral injections of the Teflon bulking agent.
- Extracorporeal magnetic innervation (ExMI) (e.g., NeoControl pelvic floor therapy system).
- Transvaginal radiofrequency or microwave surgery (e.g., SURx Transvaginal System).
- Transurethral radiofrequency tissue micro-remodeling (e.g., Renessa® System).
- Adjustable continence therapy (e.g., ACT® or ProACT™).
- Percutaneous tibial nerve stimulation (PTNS) (Urgent® PC Neuromodulation System).
- Other investigational bulking agents, (e.g., autologous fat and autologous ear chondrocytes, FemSoft Insert for the control of adult female stress urinary incontinence).

Alternative covered services:
• Pharmacotherapy.
• Behavioral modification.
• PFMT.
• Bladder training.

Background

Previously referred to as “urge incontinence or detrusor instability,” the term overactive bladder syndrome (OAB), adopted by the International Continence Society (ICS), provides a comprehensive and descriptive approach to the condition.

OAB is formally defined by ICS as:
• Urgency, which is the complaint of sudden need to void.
• With or without urge incontinence, involuntary loss of urine with urgency symptoms.
• Usually with frequency, which is the individual’s perception that he or she voids too often during the day, and is often defined as more than eight voids during waking hours.
• Usually with nocturia, which is awakening from sleep to empty the bladder.

According to the Treatment of Overactive Bladder in Women, Evidence Report #187, this operational definition was formally standardized as part of a consensus process of experts in 2002 by the ICS as part of an effort to promote health care professionals’ and researchers’ use of common terminology in the care and study of women with OAB (Hartmann, 2009).

Categories of UI include total incontinence (associated with urinary tract fistula or ectopic ureter), functional (associated with psychiatric or mobility disorders), uncategorized, overflow, post-micturition dribble, radiotherapy, and climacturia. UI can include stress incontinence, urge incontinence, mixed incontinence, total incontinence, and reversible incontinence.

Little is known about causes, and most physiology and clinical research aimed at understanding etiology is now focused on the descriptive and hypothesis development and testing phase of investigation. The most promising theories postulate abnormalities in control of bladder function resulting from aberrations in neurologic signals from the bladder (sensation) and in central and peripheral nervous system regulation.

Simple bladder testing is easily performed at the initial office visit and helps to formulate a diagnosis and appropriate treatment plan. This routinely involves a urinalysis and urine culture to rule out infection and a post-void residual volume measured via bladder scanner or urethral catheterization. Further testing, including simple cystometrogram (CMG) and uroflow, can also be easily performed in the office. Complex uroflow may be performed with a full bladder before or after simple CMG and does require special equipment.
Urodynamic testing and cystoscopy are usually performed by urology or urogynecology subspecialists. These tests are not required for first-line evaluation of OAB. Multichannel urodynamic testing requires special equipment and training. It allows precise measurement or calculation of intraurethral, intravesical, and intra-abdominal pressures during filling and emptying of the bladder. Most patients with OAB will demonstrate reduced maximum bladder capacity and early sensations on testing. Some will show spontaneous detrusor contractions and reduced compliance during filling. Cystoscopy is usually normal in OAB patients. In some patients it may show trabeculations, stones, or abnormal masses or lesions associated with bladder cancer.

Treatments for OAB that have been formally investigated include pharmacologic treatments, such as prescription medications, both pills and patches; surgeries and procedures, such as sacral neuromodulation and botulinum injections; behavioral interventions, such as behavior modification programs; bladder training; and complementary and alternative medicine, such as acupuncture and reflexology. The mainstay of treatment for overactive bladder and urge incontinence is medication. This consists of the use of bladder relaxants that prevent the bladder from contracting without the patient’s permission. When the symptoms are more severe or when conservative measures are not helping or are unsatisfactory, the treatment is surgery.

Peripheral neuromodulation techniques for neuromodulation involve stimulating the S3 nerve fibers more peripherally, at the posterior tibial nerve, or cutaneous stimulation of the pudendal nerve via an anal or vaginal probe. For the posterior tibial nerve stimulation, a needle is placed percutaneously near the ankle and is attached to an external electrical device.

The U.S. Food and Drug Administration (FDA) authorized the use of the sacral neuromodulation (SNM) device in 1997. Periurethral injection of bulking agents, such as cross-linked collagen, carbon-coated beads, calcium hydroxyapatite, and polydimethylsiloxane have been studied in randomized trials that established adequate safety and efficacy and have obtained clearance from the FDA for the treatment of adult women with stress urinary incontinence (SUI) due to intrinsic sphincteric deficiency. Guidelines from the American Urological Association (Gormley, 2012) have concluded, “Clinicians may offer peripheral tibial nerve stimulation (PTNS) as third-line treatment in a carefully selected patient population.”

The most common and the most popular surgery for stress incontinence is the sling procedure. In this operation, a narrow strip of material is used from either cadaveric tissue, autologous tissue, or soft mesh. It is applied under the urethra to provide a hammock of support and improve urethral closure.

Retropubic colposuspension is abdominal surgery in which the vaginal tissues or periurethral tissues are affixed to the pubic bone. The long-term results are good, but the surgery requires longer recuperation time and is generally only used when other abdominal surgeries are also required. While this procedure can also be performed laparoscopically, long-term results are not as good as with the open procedure.
The most effective treatment for male incontinence is implantation of an artificial urinary sphincter. This device is made from silicone and has three components that are implanted into the patient. The cuff is the portion that provides circular compression of the urethra, and therefore prevents leakage of urine from occurring. This is placed around the urethra after an incision is made in the perineum. A small fluid-filled pressure-regulating balloon is placed in the abdomen and a small pump is placed in the scrotum to be controlled by the patient. The fluid in the abdominal balloon is transferred to the urethral cuff, closing the urethra and preventing leakage of urine. When the patient needs to urinate he presses the scrotal pump, which releases the fluid back to the abdominal balloon, opening the urethra and allowing the patient to void.

Searches

AmeriHealth Caritas Pennsylvania searched PubMed and the databases of:

- UK National Health Services Centre for Reviews and Dissemination.
- Agency for Healthcare Research and Quality’s National Guideline Clearinghouse and other evidence-based practice centers.
- The Centers for Medicare & Medicaid Services (CMS).

We conducted searches on February 9, 2016. Search terms were: “overactive bladder,” “urinary incontinence,” and “stress incontinence.”

We included:

- **Systematic reviews**, which pool results from multiple studies to achieve larger sample sizes and greater precision of effect estimation than in smaller primary studies. Systematic reviews use predetermined transparent methods to minimize bias, effectively treating the review as a scientific endeavor, and are thus rated highest in evidence-grading hierarchies.
- **Guidelines based on systematic reviews**.
- **Economic analyses**, such as cost-effectiveness, and benefit or utility studies (but not simple cost studies), reporting both costs and outcomes — sometimes referred to as efficiency studies — which also rank near the top of evidence hierarchies.

Findings

Guidelines supporting medical necessity of treatments listed in this policy are taken from the American Urological Association, for sacral nerve stimulation, tibial nerve stimulation, artificial urinary sphincter (Gormley, 2015), and injectable bulking agents (Appell, 2009), and the American College of Obstetrics and Gynecology for sling procedures (ACOG, 2005).

Bulking agents have been the subject of various studies. One systematic review included two studies that found injection of bulking agents resulted in a lower rate of voiding dysfunctions than in the control group. The authors conclude that although bulking agents should not be a first-line treatment for UI, the
minimally invasive nature of the procedure should be considered (Leone Roberti Magiore U, 2015). A Cochrane review of 14 studies (n = 2004) concluded that results addressed different aspects of efficacy, and thus were not comparable (Kirchin, 2012).

Another systematic review of eight studies (n = 767) of polyacrylamide hydrogel (Bulkamid®), one of several injectable bulking agents currently in use, found 24.3 percent of women required reinjection to achieve adequate efficacy. Common adverse effects were pain at the injection site (4 percent to 14 percent) and urinary tract infections (3 percent to 7 percent). Quality of life improved significantly for the group of patients, including reductions in the number of and volume of incontinence episodes per 24-hour period (Kasi, 2016).

Systematic reviews have been conducted on sling procedures. One such review included five studies on the suburethral sling procedure among women over 65. Between 5.2 percent and 17.6 percent reported UI after surgery, and the complication rates varied from 1 percent to 26 percent, mainly bladder perforation, bladder emptying disturbances, and de novo urge (Franzen, 2015). Another study of outpatient suburethral sling in women found a post-operative continence rate of 78 percent to 88 percent, with 6.8 percent to 12 percent significantly improved; only minor complications were found in 7.2 percent to 19.8 percent of patients (Serey-Eiffel, 2015). The retropubic approach had higher morbidity than did transobturator, but both had high cure rates (Ford, 2015). A Cochrane review found a single-incision sling to be inferior to standard mid-urethral slings; the single-incision sling (TVT-Secur) was withdrawn from clinical use (Nambiar, 2014).

A review of 12 studies (n = 623) on artificial urinary sphincter for stress UI in men documented that continence, defined as one pad or no pads a day, was achieved in 61 percent to 100 percent of patients. Adverse events included infection or erosion (8.5 percent), mechanical failure (6.2 percent), and urethral atrophy (7.9 percent), while the reoperation rate was 26.0 percent (Van der Aa, 2013).

A review of 99 comparative studies found sacral neuromodulation more efficacious than antimuscarinic treatment for improving overactive bladder and quality of life (Olivera, 2016). Earlier, a systematic review of 26 studies (n = 357) found the pooled success rate of the procedure to be 92 percent, with a mean follow-up of 26 months, along with a 24 percent adverse event rate (Kessler, 2010). A systematic review of seven studies of sacral nerve stimulation for OAB documented found six of them to be “good” regarding adverse events. Surgical revision rates ranged from 3 percent to 16 percent, while 6 percent were explanted due to lack of efficacy and 5 percent to 11 percent were explanted due to infection (Siddiqui, 2010).

Tibial nerve stimulation was the topic of a 16-study review (n = 483) of men and women with urinary tract dysfunction; preliminary data showed a substantial increase in maximum cystometric capacity and bladder volume (Schneider, 2015). Another literature review found the procedure was effective in 37 percent to 100 percent of persons with overactive bladder syndrome, 41 percent to 100 percent of persons with non-obstructive urinary retention, and up to 100 percent of persons with chronic pelvic pain or painful bladder syndrome (Gaziev, 2013).
One systematic review compared quality and surgical outcomes of three types of surgery for urinary incontinence, based on 30 studies since 1990 using the authors' own scoring system. Artificial urinary sphincter was more successful than urethral bulking agents (77 to 27), and urethral bulking agents reported higher failures than urethral sling procedures and artificial urinary sphincter (both 49 to 21) (Farag, 2016). Similar results were found in another review of eight publications; cure rates for recurrent UI were 68.5 percent for midurethral sling procedures and just 38 percent for urethral bulking injections; artificial urinary sphincter shows promising results based on limited data (Nikolopoulos, 2015).

Urinary incontinence’s association with mortality has been assessed. In a systematic review and meta-analysis of 38 studies, persons with the disorder had a significantly higher risk of mortality (Hazard Ratio 2.22) than those without. Risk increased with severity of the disease. No difference in risk exists between genders (John, 2016).

One systematic review of seven studies examined the economic burden of urgency urinary incontinence in the United States. The estimated total of direct, indirect, and intangible costs for adults over age 25 was $65.9 billion in 2007, with a projected increase to $82.6 billion by 2020 (Coyne, 2014).

Policy updates:

A total of two practice guidelines/other and 18 peer-reviewed references were added to this version of the policy, many of them recent publications or systematic reviews/meta-analyses.

Summary of clinical evidence:

<table>
<thead>
<tr>
<th>Citation</th>
<th>Content, Methods, Recommendations</th>
</tr>
</thead>
<tbody>
<tr>
<td>Farag (2016)</td>
<td><strong>Key points:</strong></td>
</tr>
<tr>
<td>Comparison of</td>
<td>• Systematic review of 30 studies; quality of reporting was 43 percent to 81 percent.</td>
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<tr>
<td>quality and</td>
<td>• Artificial urinary sphincter was more successful than urethral bulking agents (77 to 27).</td>
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<tr>
<td>surgical outcomes</td>
<td>• Urethral bulking agents had more failures than urethral sling procedures (49 to 21).</td>
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<tr>
<td>of various surgical treatments for UI</td>
<td>• Urethral bulking agents had more failures than artificial urinary sphincter (49 to 21).</td>
</tr>
<tr>
<td>Kasi (2016)</td>
<td><strong>Key points:</strong></td>
</tr>
<tr>
<td>Efficacy and</td>
<td>• Systematic review of eight studies (n = 767) of Bulkmid®, an injectable bulking agent.</td>
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<tr>
<td>adverse events of</td>
<td>• 24.3 percent of women required reinjection to achieve adequate efficacy.</td>
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<td>• Most frequent adverse effects were pain at the site of injection (4 percent to 14 percent) and urinary tract infections (3 percent to 7 percent).</td>
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<tr>
<td></td>
<td>• Incontinence episodes/24 hours and ml/24 hours were significantly reduced after one year.</td>
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<tr>
<td>Serey-Eiffel (2015)</td>
<td><strong>Key points:</strong></td>
</tr>
</tbody>
</table>
## Continence and complications after outpatient suburethral sling for UI in women

- Systematic review of literature to assess efficacy, complication, and feasibility of outpatient suburethral slings for stress UI in women.
- 78 percent to 88 percent of patients were continent postoperatively.
- 6.8 percent to 12.0 percent of patients were significantly improved.
- No major complication occurred; minor complications occurred in 7.2 percent to 19.8 percent of patients.
- 70 percent to 100 percent of patients discharged on post-operative day 0.
- Satisfaction rate was 89.4 percent to 95.0 percent.

### Schneider (2015)

**Outcomes of tibial nerve stimulation for lower urinary tract dysfunction**

**Key points:**
- Meta-analysis of 16 studies (n = 469).
- In acute and chronic tibial nerve stimulation (TNS), mean increase of maximum cystometric capacity ranged from 56 to 132 mL and 49 to 150 mL.
- Mean increase of bladder volume at first detrusor activity ranged from 44 to 92 mL and 93 to 121 mL, respectively.
- No TNS-related adverse effects were reported.

### Van der Aa (2013)

**Success and adverse events for artificial urinary sphincter for UI in men**

**Key points:**
- Systematic review of 12 reports (n = 623).
- Continence (patient-reported pad use) of 0 – 1 pads per day occurred in 61 percent to 100 percent of patients.
- Infection or erosion occurred in 8.5 percent of cases, mechanical failure in 6.2 percent, and urethral atrophy in 7.9 percent.
- Reoperation rate was 26.0 percent.

### Siddiqui (2010)

**Efficacy and adverse events of sacral nerve stimulation for overactive bladder**

**Key points:**
- Systematic review of seven studies.
- Surgical revision rates ranged from 3 percent to 16 percent.
- Six percent of patients were explanted due to lack of efficacy, and 5 percent to 11 percent were explanted due to infection.

## References

**Professional society guidelines/other:**


**Peer-reviewed references:**


**CMS National Coverage Determinations (NCDs):**


**Local Coverage Determinations (LCDs):**


**Commonly submitted codes**

Below are the most commonly submitted codes for the service(s)/item(s) subject to this policy. This is not an exhaustive list of codes. Providers are expected to consult the appropriate coding manuals and bill accordingly.

<table>
<thead>
<tr>
<th>CPT Code</th>
<th>Description</th>
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<tr>
<td>51840</td>
<td>Anterior vesicourethropexy, or urethropexy (e.g., MarChetti-Krantz, Burch); simple</td>
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<td>51841</td>
<td>Anterior vesicourethropexy, or urethropexy (e.g., MarChetti-Krantz, Burch); complicated (eg, secondary repair)</td>
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<td>51845</td>
<td>Abdomino-vaginal vesical neck suspension, with or without endoscopic control (e.g., Stamey, Raz, modified Pereyra)</td>
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<tr>
<td>51992</td>
<td>Laparascopy; surgical; sling operation for stress incontinence</td>
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<tr>
<td>53440</td>
<td>Sling operation for correction of male urinary incontinence</td>
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<tr>
<td>53448</td>
<td>Removal and replacement of inflatable urethral/bladder neck sphincter including pump, reservoir, cuff through an infected field in the same operation session including irrigation and debridement of infected tissue</td>
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<tr>
<td>57220</td>
<td>Plastic operation on urethral sphincter, vaginal approach (e.g., Kelly urethral plication)</td>
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<tr>
<td>57240</td>
<td>Anterior colporrhaphy, repair of cystocele with or without repair of urethrocele</td>
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<tr>
<td>57267</td>
<td>Insertion of mesh or other prosthesis for repair of pelvic floor defect, each site (anterior, posterior compartment), vaginal approach</td>
<td>Add-on code</td>
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<td>57287</td>
<td>Removal or revision of sling for stress incontinence (e.g., fascial or synthetic)</td>
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<td>N32.81</td>
<td>Overactive bladder</td>
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<td>N39.41</td>
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<td>R32</td>
<td>Unspecified urinary incontinence</td>
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