BlueCross BlueShield of Alabama

Name of Policy:
Temporary Prostatic Stent

Policy #: 213
Category: Medicine

Latest Review Date: September 2012
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:

Prostatic obstruction is a common condition with a variety of etiologies. Benign prostatic hyperplasia (BPH) is the most common etiology, but obstruction may also occur acutely after surgical treatment for BPH, prostatic cancer or after radiation therapy. Intraprostatic stenting has been investigated as a short-term treatment option permitting volitional urination as an alternative to the commonly used Foley catheter in which urine is collected in an external bag. In addition to volitional urination, the ideal temporary stent would be one that could be easily inserted and removed without migration, permitting adequate emptying of the bladder without disrupting the external sphincter such that continence could be maintained.

The Spanner™ stent is composed of a proximal balloon to prevent distal displacement, a urine port situated cephalad to the balloon and a reinforced stent of various lengths to span most of the prostatic urethra. The distal anchor compresses the device against the sides of the meatus, thus minimally obstructing the urine flow. Sutures attach a distal anchor mechanism. Finally, a retrieval suture extends to the meatus and deflates the proximal balloon when pulled. The device is inserted in an outpatient procedure under topical anesthesia.

Note: This policy does not address the use of permanent prostatic stents. The Urolume is an example of an FDA approved **permanent** prostatic stent. This wire mesh device is placed into the urethra, where it is slowly incorporated into the urethral wall. This policy only addresses temporary stents, which are designed to be removable.

Policy:

A **temporary prostatic stent does not meet** Blue Cross and Blue Shield of Alabama's medical criteria for coverage and is considered **investigational**.

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:

Literature Review

This policy was originally created in 2004 and regularly updated with searches of the MEDLINE database. The most recent literature search was performed for the period July 2011 through July 2012. Following is a summary of the key literature to date:

There is minimal published data regarding the Spanner stent or any temporary prostatic urethral stent. Corica et al published the results of a case series of 30 patients who had obstruction of the prostatic urethra. The Spanner stent was inserted and remained in situ for between 1 and 98 days (mean 57 days). The maximum urinary flow rate improved from 8.2 mL/sec to 11.6 mL/sec, while the mean post void residual improved from 312 mL to 112.3 mL. There was temporary self-limited incontinence during the first week in 11 of the 30 patients. There were no significant complications.

A European research group conducted studies for two new designs of removable stents in a total of 143 subjects. Unsatisfactory outcomes were reported for both models; the stents required early removal due to migration and other sources of pain with a median retention of less than 105 days.

One randomized controlled trial (RCT) that evaluates the Spanner (Sp) prostatic stent has been published. Findings were published in 2008 by Dineen and colleagues. The study evaluated the impact of the Spanner stent on management of voiding symptoms, irritative symptoms, and bother after transurethral microwave thermotherapy (TUMT). (1) Patients (n=186) were randomly assigned to the Sp (n=100) or standard of care (SOC, n=86) after TUMT and 3 to 10 days of routine catheterization. After catheter removal, the SOC group received no further treatment until follow-up visits. Primary outcomes evaluated included the International Prostate Symptom Score (IPSS) voiding subscore, IPSS irritative subscore, voiding diary data, and Benign Prostatic Hyperplasia Impact Index 7 to 10 days before TUMT and repeated 1, 2, 4 (stent removal), 5, and 8 weeks after stent insertion. The IPSS voiding and irritative subscores showed statistically significant improvement at week 1 for the Sp group but no significant differences at weeks 2, 4, 5, and 8. For the individual IPSS voiding and irritative questions of incomplete emptying, there were no significant differences between the Sp and SOC groups at any visit. Overall, individual IPSS irritative questions did not differ significantly between the Sp and SOC groups at 1, 2, and 4 weeks after stent insertion. From the voiding diary data, the feeling of incomplete emptying, terminal dribble, and leakage were not significantly different between the Sp and SOC groups at any visit. On the Benign Prostatic Hyperplasia Impact Index, the Sp group was less bothered during the time of stent use (2 weeks). The remaining weeks for this index were similar in both groups. While this study showed statistically significant changes in some outcome measures, the study has a number of limitations. First, participants or practitioners were not blinded to the treatment, so potential biases could have occurred on reporting the outcome measures. Second, no information is given about dropout rates or missing data. Finally, the clinical significance of many of the findings is not known. Thus, these data are inconclusive regarding the role of temporary prostatic stents for prostatic obstruction conditions.

Another report on the Spanner stent, published in 2007, described repeated temporary stent use in 43 consecutive patients with bladder-outlet obstruction who were unfit for surgery. It was reported that more than half of the patients (63%) had unsatisfactory outcomes; the remaining 37% were considered to have had satisfactory outcomes, either with a stent in situ after a mean of 5 changes or stent-free after a successful voiding trial.

In 2006, Kijvikai and colleagues conducted a study in Europe to assess the efficacy and safety of 2 versions of a blind placement temporary prostatic stent (BPS-1 and BPS-2) in the treatment of patients with benign prostatic obstruction. A total of 55 men were enrolled in the trial. Spontaneous voiding was achieved in all patients immediately after stent insertion, with improvements in voiding parameters and symptom scores. In patients with the BPS-1, migration occurred in 85%. In patients with the BPS-2, migration occurred in 5%. The median indwelling time of the stent was 16 days for the BPS-1 and 38 days for the BPS-2. Removal was successful in all but 1 case (BPS-2). The authors concluded that the BPS-1 and BPS-2 are not suitable for clinical practice because of the significantly high migration rate (BPS-1) and voiding parameters and symptom scores (BPS-2) that were not significantly improved. Given the study location and lack of FDA approval for these devices, these data are insufficient to draw conclusions regarding the use of these devices.

In 2005 and 2006, van Dijk and colleagues conducted studies for 2 designs (hourglass-shaped and bell-shaped) of removable stents in a total of 143 subjects. Unsatisfactory outcomes were reported for both models; the stents required early removal due to migration and other sources of pain, with a median retention of less than 105 days.

In 2008, Vanderbrink and colleagues published a review of the use of the temporary prostatic stent. The report concluded that "….a major disadvantage of temporary prostatic stents is that they have a small lumen that can result in urinary retention secondary to clot–induced impairment of catheter patency, when placed in the immediate post-TUMT treatment."

In 2011, Chao et al published a small case series that evaluated the Memokath 028 temporary prostatic stent for preventing urinary obstructive symptoms after prostate brachytherapy. Stent removal was planned for 6 months after implant. Seven of 20 patients (35%) requested early stent removal due to adverse events; 3 of these reported urinary incontinence and 2 reported discomfort. The authors concluded that use of stenting in this situation is feasible but has a relatively high rate of adverse effects; they recommended that future studies focus on patients at highest risk of urinary obstruction.

Summary
Data are inconclusive regarding the role of temporary prostatic stents for prostatic obstructive conditions. This procedure has not been shown to improve the net health outcome. Therefore, the use of temporary prostatic stents is considered investigational.

Practice Guidelines and Position Statements
Although previous versions of the American Urological Association guideline on the management of benign prostatic hyperplasia included a statement on temporary prostatic stents, this technology was not mentioned in the current version of the guideline (revised 2010). No other relevant practice guidelines or position statements were identified.

Key Words:
Temporary prostatic stent, Spanner temporary prostatic stent, intraprostatic stenting

Approved by Governing Bodies:

The Spanner™ temporary prostatic stent received approval from the U.S. Food and Drug Administration (FDA) on December 14, 2006 through the premarket approve or PMA process. The device is intended "for temporary use (up to 30 days) to maintain urine flow and allow voluntary urination in patients following minimally invasive treatment for benign prostatic hyperplasia (BPH) and after initial post-treatment catheterization."

The Memokath 028 is a new prostatic stent which is also temporary. It is a nickel-titanium stent which is made by PNN Medical (Denmark). **This stent does not have FDA approval.**

Benefit Application:

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

ITS: Home Policy provisions apply
BellSouth/AT&T contracts: No special consideration
FEP contracts: FEP does not consider investigational if FDA approved. Will be reviewed for medical necessity.
Wal-Mart: Special benefit consideration may apply. Refer to member's benefit plan.
Pre-certification/Pre-determination requirements: Not applicable

Current Coding:

CPT codes:

53855	Insertion of a temporary prostatic urethral stent, including urethral measurement

Previous Coding:

CPT codes:

0084T	Insertion of a temporary prostatic urethral stent **(deleted 01/01/2010)**

References:

1. Blue Cross Blue Shield Association. Technology Evaluation Center (TEC) Assessment, Section: Medicine. September 2011.
2. Chao ST, Angermeier K, Klein EA et al. Prophylactic uretheral stenting with memokath 028SW in prostate cancer patients undergoing prostate 125l seed implants: phase I/II study. J Contemp Brachytherapy 2011; 3(1):18-22.
3. Corica AP, Larson BT et al. A novel temporary prostatic stent for the relief of prostatic urethral obstruction, BJU Int 2004; 93:346-48.

4. Dineen MK, Shore ND Lumerman JH, et al. Use of a temporary prostatic stent after transurethral microwave thermotherapy reduced voiding symptoms and bother without exacerbating irritative symptoms. Urology 2008; 71(5):873-7.
5. Grimsley SJ, Khan MH, Lennox E et al. Experience with the spanner prostatic stent in patients unfit for surgery: an observational study. J Endourol 2007; 21(9):1093-6.
6. Kijvikai K, van Dijk M, Pes PL et al. Clinical utility of "blind placement" prostatic stent in patients with benign prostatic obstruction: a prospective study. Urology 2006; 68(5):1025-30.
7. Shore ND, Dineen MK, Saslawsky MJ et al. A temporary intraurethral prostatic stent relieves prostatic obstruction following transurethral microwave thermotherapy. J Urol 2007; 177(3):1040-6
8. van Dijk MM, Mochtar CA, Wijkstra H et al. Hourglass-shaped nitinol prostatic stent in treatment of patients with lower urinary tract symptoms due to bladder outlet obstruction. Urology 2005; 66(4):845-9.
9. van Dijk MM, Mochtar CA, Wijkstra H et al. The bell-shaped nitinol prostatic stent in the treatment of lower urinary tract symptoms: experience in 108 patients. Eur Urol 2006; 49(2):353-9.
10. Vanderbrink BA, Rastinehad AR, Badlani GH. Prostatic stents for the treatment of benign prostatic hyperplasia. Curr Opin Urol 2007; 17(1):1-6.

Policy History:

Medical Policy Group, December 2004 **(4)**
Medical Policy Administration Committee, January 2005
Available for comment January 21-March 7, 2005
Medical Policy Group, December 2006 **(1)**
Medical Policy Group, December 2008 **(1)**
Medical Policy Group, October 2010 **(1)**
Medical Policy Group, September 2011**(1)**; Updated Description, Key Points, & References
Medical Policy Panel, September 2012
Medical Policy Group, September 2012 **(1)** Update to Key Points related to literature search; no change to policy statement
Medical Policy Group, February 2013 **(1)**: Active policy but no longer scheduled for literature reviews and updates.