

Corporate Medical Policy

Temporary Prostatic Stent

File Name:	temporary_prostatic_stent
Origination:	1/2010
Last CAP Review:	11/2011
Next CAP Review:	11/2012
Last Review:	11/2011

Description of Procedure or Service

Prostatic obstruction is a common condition with a variety of etiologies. Obstruction may occur acutely after surgical treatment for benign prostatic hyperplasia (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™ (AbbeyMoor Medical) temporary 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 is shaped like a teardrop and positioned in the distal meatus. As the patient voids, the force of the urine compresses the device against the sides of the meatus, thus minimally obstructing the urine flow. A distal anchor mechanism is attached by sutures. Finally, a retrieval suture extends to the meatus and deflates the proximal balloon when pulled. The insertion of this device may be as an outpatient procedure with the patient under topical anesthesia or an office procedure without anesthesia.

The Spanner™ temporary prostatic stent received approval from the U.S. Food and Drug Administration (FDA) in December 2006 through the premarket approval (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 BPH and after initial post-treatment catheterization.” In June 2009, the FDA approved a PMA supplement allowing for a structural change in the Spanner device that includes a change to a high durometer silicone sleeve, which the company states adds to the patient's comfort with the device.

Pnn Medical (Denmark) also makes a temporary prostatic stent, the Memokath™ 028. This is a nickeltitanium stent that is inserted in an outpatient procedure. The Memokath device has not received premarket approval from the U.S. Food and Drug Administration (FDA).

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.

******Note: This Medical Policy is complex and technical. For questions concerning the technical language and/or specific clinical indications for its use, please consult your physician.***

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Policy

BCBSNC will not provide coverage for the use of a temporary prostatic stent. It is considered investigational. BCBSNC does not cover investigational services.

Benefits Application

This medical policy relates only to the services or supplies described herein. Please refer to the Member's Benefit Booklet for availability of benefits. Member's benefits may vary according to benefit design; therefore member benefit language should be reviewed before applying the terms of this medical policy.

When Temporary Prostatic Stent is covered

Not Applicable.

When Temporary Prostatic Stent is not covered

The use of a temporary prostatic stent is not covered. It is considered investigational and BCBSNC does not cover investigational services.

Policy Guidelines

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

The American Urological Association guideline for the management of BPH includes the following statement regarding stents: "Because stents are associated with significant complications, such as encrustation, infection and chronic pain, their placement should be considered only in high-risk patients, especially those with urinary retention." No specific language for temporary stents is included in the guideline.

Billing/Coding/Physician Documentation Information

This policy may apply to the following codes. Inclusion of a code in this section does not guarantee that it will be reimbursed. For further information on reimbursement guidelines, please see Administrative Policies on the Blue Cross Blue Shield of North Carolina web site at www.bcbsnc.com. They are listed in the Category Search on the Medical Policy search page.

Applicable service codes: 53855

BCBSNC may request medical records for determination of medical necessity. When medical records are requested, letters of support and/or explanation are often useful, but are not sufficient documentation unless all specific information needed to make a medical necessity determination is included.

Scientific Background and Reference Sources

BCBSA Medical Policy Reference Manual [Electronic Version]. 2.01.70, 9/10/09.

Senior Medical Director review - 12/09.

U.S. Food and Drug Administration (FDA). Approval Order P060010 for the Spanner™ Temporary

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Prostatic Stent. Retrieved on November 15, 2010 from http://www.accessdata.fda.gov/cdrh_docs/pdf6/p060010a.pdf

American Urological Association (AUA). Guideline on the management of benign prostatic hyperplasia. Retrieved on November 15, 2010 from www.auanet.org/content/guideline-and-quality-care/clinical-guidelines.cfm?sub=bph.

BCBSA Medical Policy Reference Manual [Electronic Version]. 2.01.70, 9/16/10.

Specialty Matched Consultant Advisory Panel review 12/2010

BCBSA Medical Policy Reference Manual [Electronic Version]. 2.01.70, 9/1/11

Specialty Matched Consultant Advisory panel review 11/2011

Policy Implementation/Update Information

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| 1/5/10 | New policy issued. The use of a temporary prostatic stent is considered investigational. (pmo) |
| 6/22/10 | Policy Number(s) removed (amw) |
| 1/18/11 | Specialty Matched Consultant Advisory Panel review 12/2010. References updated. Policy Guidelines updated. (mco) |
| 11/8/11 | References updated. Description section updated to include product information for the Memokath™ 028, a new non-FDA approved temporary prostatic stent. No changes to Policy Statement.(mco) |
| 12/20/11 | Specialty Matched Consultant Advisory Panel review 11/2011. No changes to Policy statement. (mco) |

Medical policy is not an authorization, certification, explanation of benefits or a contract. Benefits and eligibility are determined before medical guidelines and payment guidelines are applied. Benefits are determined by the group contract and subscriber certificate that is in effect at the time services are rendered. This document is solely provided for informational purposes only and is based on research of current medical literature and review of common medical practices in the treatment and diagnosis of disease. Medical practices and knowledge are constantly changing and BCBSNC reserves the right to review and revise its medical policies periodically.