Public Statement:

Prostatic obstruction of the urethra is a common condition with several causes. Intraprostatic stenting has been investigated as an option to relieve urinary obstruction. Temporary prostatic stenting has not been shown to improve health outcomes, and is not covered. Permanent urethral stenting is covered in some men with urinary obstruction who meet medical policy criteria.

Medical Policy Statement:

1) Use of a temporary prostatic stent is considered investigational and is not covered.
2) Use of the UroLume Endoprosthesis is considered medically necessary and is covered for men with:
   a. Recurrent bulbar urethral stricture
   b. Chronically obstructed membranous urethra due to benign prostatic hypertrophy who cannot tolerate surgical correction
3) The procedure may be performed more than once, if a second prosthesis is necessary or if the prosthesis must be removed.

Limits:

The UroLume Endoprosthesis is not covered for:
1) Stricture greater than 3.0 cm in length
2) Stricture that is not recurrent and for which other therapy has failed
3) Any other indication

Background:

Temporary stents:

Dineen et al conducted a randomized study to evaluate the ability of a temporary prostatic stent (Spanner [Sp]) to manage voiding symptoms, irritative symptoms, and bother after transurethral microwave thermotherapy (TUMT) (Dineen, 2008). Patients were randomized to the Sp or standard of care 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 shows 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 can occur 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.

Kijvikai et al conducted a study in Europe to assess the efficacy and safety of two versions of a blind placement temporary prostatic stent (BPS-1 and BPS-2) in the treatment of patients with benign prostatic obstruction (Kijvikai, 2006). 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, and 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.

Vanderbrink et al conclude that “….a major disadvantage of temporary prostatic stents is that they have a small lumen that can result in an urinary retention secondary to clot–induced impairment of catheter patency, when placed in the immediate post-TUMT treatment” (Vanderbrink, 2007).

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.

**Permanent Stents:**

UroLume Endoprosthesis is a tubular braided mesh cylinder made of high strength implant grade super alloy wire. The braided mesh is designed to expand radially after deployment to hold open sections of the bulbar urethra that obstruct flow of urine. FDA pre-market approval of the device was given May 5, 1996, ‘for use in men to relieve urinary obstruction secondary to recurrent benign bulbar urethral strictures less than 3.0 cm in length located distal to the external sphincter and proximal to the bulbar scrotal junction.’ The UroLume is not intended as in initial treatment for bulbar urethral strictures nor for the treatment of structures outside the bulbar urethra. The UroLume is an alternative treatment for the patient in whom previous treatment methods (dilation, urethrotomy or urethroplasty) have been unsuccessful (i.e., treatment was not effective initially in relieving stricture disease or there has been recurrence of stricture formation necessitating further treatment).

**References:**


Application to Products

This policy applies to ARBenefits. Consult ARBenefits Summary Plan Description (SPD) for additional information.

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