CRYOSURGICAL ABLATION OF THE PROSTATE (CSAP)
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COVERAGE:

Cryosurgical Ablation of the Prostate (CSAP) is considered medically necessary for the treatment of clinically localized or locally advanced prostatic cancer or other non-malignant prostatic conditions.

DESCRIPTION:

CSAP or Targeted Cryoablation of Prostate Cancer (TCAP) is a technique to control a localized or locally advanced disease (such as cancer) by a cryo-destructive method. Ablation is the removal of tissue by destroying it with extreme temperatures. This technique requires several cryoprobes placed in the prostate under ultrasound guidance in a configuration that depends on the tumor location and thermal protection of the urethra. Freezing starts anteriorly to prevent obstruction of the ultrasound beam. Thermo-sensors of the cryoprobes enable monitoring of the cryosurgical ice ball and determination of the number of freezes. Preoperative diagnosis and staging is accomplished by ultrasound-guided biopsies. CSAP may require pretreatment with androgen medications, such as testosterone or androsterone. A bilateral vasectomy may be performed prior to or in conjunction with the cryosurgery. A urologist and a radiologist always perform cryosurgery together. Repeated treatment sessions are not uncommon.

The advantages of this cryosurgical technique are:

• treatment of prostatic cancers without radical prostatectomy procedures (less invasive),
• less blood loss,
• decreased hospital stays,
• reduced health care costs, and
• minimally associated morbidity.

Some complications of this procedure may include:

• incomplete ablation of prostate cancers,
• incontinence,
• impotence,
• rectal freezing from inadequate monitoring of the freezing process,
• urethrocutaneous and urethrorectal fistula formations, and
• urethral tissue sloughing.

RATIONALE:
CSAP is one of the methods of management of clinically localized or locally advanced prostate cancer. This policy was initially based on the 1993 American Urological Association (AUA) position statement that CSAP is considered “investigational”. At that time, it was important to acknowledge that the scientific literature related to the treatment of prostate cancer had imperfections. There were few randomized trials, few patients enrolled in studies, and differences in outcome measurements.

In 1998, the Agency for Health Care Policy and Research (AHCPR) concluded; “Cryosurgery has resulted in the biochemical disease-free survival of some patients who have had recurrent prostate cancer following radiation therapy, the effectiveness in salvaging such patients remains unclear because the number of patients treated has been small and the follow-up periods have been relatively short.”

In 1999, Medicare limited coverage to allow CSAP for patients with clinically localized prostate cancer. Blue Cross Blue Shield Association’s (BCBSA) position was based on a 2001 BCBSA TEC Assessment, focusing on patients with clinically localized prostate cancer. The conclusions contrasted with the Centers of Medicare and Medicaid Services (CMS) analysis supporting Medicare’s decision that CSAP is eligible for coverage. While the TEC Assessment sought data on health outcomes, the CMS Assessment used an intermediate outcome, changes, such as in Prostate Specific Antigen (PSA) levels. CMS states, “Data shows that a significant number of patients are able to sustain undetectable levels of PSA for a period to time of at least 24 months... This compares favorably with the biopsy data following external beam irradiation.”

In March 2001, a five-center institutional study team reported their experience with CSAP compared to conformal radiotherapy and brachytherapy. Combined, 975 patients were studied, of whom 238 were low risk, 321 were moderate risk, 385 were high risk, and 38 were undetermined. The five year rate for non-elevating post-CSAP PSA level for medium risk patients ranged between 60% and 76% and for high risk patients it was 41%. Approximately 18% of the patients were found to have a positive biopsy following the CSAP procedure. These results placed CSAP between radiotherapy and brachytherapy in effectiveness. Morbidities seemed comparable, with impotence rates higher and rectal injury rates lower after CSAP than after radiotherapy.

Finally, in May 2002, the AUA recognized a seven-year outcomes study, using targeted CSAP as the primary treatment of locally confined and locally advanced prostate cancer. CSAP was shown to equal or surpass the outcome data of external beam irradiation, 3-Dimensional conformal radiation, and brachytherapy. A series of 590 patients underwent
targeted CSAP. A mean follow up time for all patients was 5.43 years. The seven-year biochemical disease free survival (bDFS) rates for low-, medium-, and high-risk patients were 61%, 68%, and 61% respectively. bDFS is defined as three successive increases in PSA level by the American Society for Therapeutic Radiology and Oncology (ASTRO). The rate of positive biopsy was 13%. After the positive biopsy, 32 patients underwent repeat CSAP. The rates of morbidity were modest, and no serious complications were observed.

PRICING:

None

REFERENCES:

• Grampisas, S.A., Miller, G.J., et al. "Salvage radical prostatectomy after failed transperineal cryotherapy: histologic findings from...


- AUA "Cryosurgical Ablation of the Prostate in Men with an Unfavorable Presentation of Clinically Localized Prostate Cancer."


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