POLICY STATEMENT:

I. Based upon our criteria and review of the peer-reviewed literature, cryosurgery for prostate cancer has been medically proven to be effective and is considered a medically appropriate treatment option for low volume, primary disease. (Low volume is defined as PSA - prostate-specific antigen - less than 10ng/ml, a Gleason score less than 7 and localized prostate cancer.)

II. Based upon our criteria and assessment of peer-reviewed literature, salvage cryosurgery for recurrent prostate cancer is considered a medically appropriate treatment option for those patients who have recurrent localized disease and who have failed a trial of radiation therapy as a primary treatment. One of the following criteria must be met:
   A. Stage T2b or below; or
   B. Gleason score less than 9; or
   C. PSA less than 8 ng/ml.

III. Based upon our criteria and assessment of peer-reviewed literature, salvage cryosurgery for recurrent prostate cancer after failure of any treatments other than radiation therapy as a primary therapy has not been medically proven effective and is considered investigational.

Refer to Corporate Medical Policy #6.01.16 regarding Brachytherapy or Radioactive Seed Implantation for Prostate Cancer.

POLICY GUIDELINES:

The Federal Employee Health Benefit Program (FEHBP/FEP) requires that procedures, devices or laboratory tests approved by the U.S. Food and Drug Administration (FDA) may not be considered investigational and thus these procedures, devices or laboratory tests may be assessed only on the basis of their medical necessity.

DESCRIPTION:

Cryosurgical ablation of the prostate is an alternative method of treatment for prostate cancer. The cryoablation technique involves the use of transrectal ultrasound-guided percutaneous placement of cryoprobes to freeze prostate tissue in order to produce well-demarcated areas of cell injury and destruction. Refinements in the technique with transrectal ultrasonography, improved cryosurgical instrumentation and the use of commercial urethral warmers have decreased the complications associated with the early attempts at cryosurgery. The benefits of cryosurgery of the prostate include a shorter surgical procedure time with minimal blood loss.

RATIONALE:

Published studies have demonstrated that patients with low volume, localized, primary prostate cancer undergoing cryosurgery remain biochemically disease-free up to 3 years. Surgically related morbidities of cryosurgery of the prostate have compared favorably to those reported for radical prostatectomy and radiation therapy. The available data suggests that select patients with radioresistant cancer have benefited from the use of cryosurgery as a salvage therapy. To date, case studies indicate that at least, in the short-term, cryosurgery is better tolerated than open salvage surgery.
and can be considered a treatment option for men who would not be candidates for open surgery. Complication rates can be minimized through improvements in technique and instrumentation and in experienced cryosurgeons.

**CODES:**

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**REFERENCES:**


*BlueCross BlueShield Association Technology Evaluation Center (TEC). Cryoablation for the primary treatment of clinically localized prostate cancer. 2001 Sep;16(6).


*key article
KEY WORDS:
Cryoablation of the prostate

CMS COVERAGE FOR MEDICARE PRODUCT MEMBERS

There is currently a National Coverage Determination (NCD) for Cryosurgery of the Prostate. Please refer to the following NCD website for Medicare Members: http://www.cms.gov/medicare-coverage-database/details/ncd-details.aspx?NCDId=123&ncdver=1&bc=AgAAgAAAAAAA&