

MEDICAL POLICY

SUBJECT: CRYOSURGERY FOR PROSTATE CANCER	EFFECTIVE DATE: 10/18/01 REVISED DATE: 11/15/01, 10/16/02, 08/21/03, 07/15/04, 07/21/05, 07/20/06, 07/19/07, 07/17/08, 07/16/09, 08/19/10, 08/18/11, 08/16/12, 08/15/13, 08/21/14, 08/20/15, 07/21/16, 07/20/17, 07/19/18
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<ul style="list-style-type: none">• <i>If a product excludes coverage for a service, it is not covered, and medical policy criteria do not apply.</i>• <i>If a commercial product (including an Essential Plan product) or a Medicaid product covers a specific service, medical policy criteria apply to the benefit.</i>• <i>If a Medicare product covers a specific service, and there is no national or local Medicare coverage decision for the service, medical policy criteria apply to the benefit.</i>	

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.

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The American Urological Association (AUA), in collaboration with the American Society for Radiation Oncology (ASTRO) and Society of Urologic Oncology (SUO), released a new evidence-based clinical guideline for the appropriate management of localized prostate cancer in 2017. The guidelines state the following recommendations:

1. Clinicians may consider whole gland cryosurgery in low- and intermediate-risk localized prostate cancer patients who are not suitable for either radical prostatectomy or radiotherapy due to comorbidities yet have >10 year life expectancy. (Expert Opinion).
2. Clinicians should inform localized prostate cancer patients considering whole gland cryosurgery that cryosurgery has similar progression-free survival as did non-dose escalated external beam radiation (also given with neoadjuvant hormonal therapy) in low- and intermediate-risk disease, but conclusive comparison of cancer mortality is lacking. (Conditional Recommendation; Evidence Level: Grade C).
3. Clinicians should inform localized prostate cancer patients considering cryosurgery that it is unclear whether or not concurrent ADT improves cancer control, though it can reduce prostate size to facilitate treatment. (Clinical Principle).
4. Clinicians should inform localized prostate cancer patients considering whole gland cryosurgery that erectile dysfunction is an expected outcome. (Clinical Principle).
5. Clinicians should inform localized prostate cancer patients considering whole gland cryosurgery about the adverse events of urinary incontinence, irritative and obstructive urinary problems. (Strong Recommendation; Evidence Level: Grade B).
6. Defects from prior transurethral resection of the prostate are a relative contraindication for whole gland cryosurgery due to the increased risk of urethral sloughing. (Clinical Principle).

CODES: Number Description

Eligibility for reimbursement is based upon the benefits set forth in the member's subscriber contract.

CODES MAY NOT BE COVERED UNDER ALL CIRCUMSTANCES. PLEASE READ THE POLICY AND GUIDELINES STATEMENTS CAREFULLY.

Codes may not be all inclusive as the AMA and CMS code updates may occur more frequently than policy updates.

Code Key: Experimental/Investigational = (E/I), Not medically necessary/ appropriate = (NMN).

CPT: 55873 Cryosurgical ablation of the prostate (includes ultrasonic guidance and monitoring)
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HCPCS: C2618 Probe/needle, cryoablation

ICD10: C61 Malignant neoplasm of prostate
 C79.82 Secondary malignant neoplasm of genital organs
 D07.5 Carcinoma in situ of prostate
 Z85.46 Personal history of malignant neoplasm of prostate

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*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=AgAAgAAAAA&>