



CIGNA MEDICAL COVERAGE POLICY

The following Coverage Policy applies to all plans administered by CIGNA Companies including plans administered by Great-West Healthcare, which is now a part of CIGNA.

Subject Cryoablation for Prostate Cancer

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Coverage Policy Number 0199

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Hyperlink to Related Coverage Policies

- Brachytherapy for Prostate Cancer
- Gene-Based Testing for Prostate Cancer Screening, Detection and Disease Monitoring
- Prostate-Specific Antigen (PSA) Screening for Prostate Cancer
- Proton Beam Therapy for Prostate Cancer
- Transrectal Ultrasound (TRUS)

INSTRUCTIONS FOR USE

Coverage Policies are intended to provide guidance in interpreting certain **standard** CIGNA HealthCare benefit plans as well as benefit plans formerly administered by Great-West Healthcare. Please note, the terms of a participant's particular benefit plan document [Group Service Agreement (GSA), Evidence of Coverage, Certificate of Coverage, Summary Plan Description (SPD) or similar plan document] may differ significantly from the standard benefit plans upon which these Coverage Policies are based. For example, a participant's benefit plan document may contain a specific exclusion related to a topic addressed in a Coverage Policy. In the event of a conflict, a participant's benefit plan document **always supercedes** the information in the Coverage Policies. In the absence of a controlling federal or state coverage mandate, benefits are ultimately determined by the terms of the applicable benefit plan document. Coverage determinations in each specific instance require consideration of 1) the terms of the applicable group benefit plan document in effect on the date of service; 2) any applicable laws/regulations; 3) any relevant collateral source materials including Coverage Policies and; 4) the specific facts of the particular situation. Coverage Policies relate exclusively to the administration of health benefit plans. Coverage Policies are not recommendations for treatment and should never be used as treatment guidelines. Proprietary information of CIGNA. Copyright ©2010 CIGNA

Coverage Policy

CIGNA covers cryoablation for prostate cancer as medically necessary for EITHER of the following:

- stage T1 (i.e., clinically inapparent tumors), stage T2 (i.e., tumor confined within the prostate), or stage T3 (i.e., tumor locally advanced) when lymph nodes are negative for cancer
- salvage therapy for recurrent cancer following failure of radiation when the cancer is confined to the prostate

CIGNA does not cover cryoablation for prostate cancer for ANY of the following indications because it is considered experimental, investigational or unproven (this list may not be all-inclusive):

- salvage therapy for recurrent cancer following failure of therapy other than radiation (e.g., radical prostatectomy)
- stage T4 tumors (i.e., the tumor is fixed to or invades adjacent structures)
- palliation of individuals with metastatic disease

General Background

Cryoablation, also called cryosurgery, cryotherapy, cryosurgical ablation of the prostate (CSAP), is a surgical technique that uses percutaneously inserted cryoprobes to freeze and destroy, cancerous prostate tissue. Cryoablation is a minimally invasive procedure associated with minimal damage to the surrounding tissue, minimal blood loss, shorter hospital stays, high rates of negative biopsies following ablation, and low morbidity (Korpan, 2007; Lam, et al., 2007; Gage and Baust, 2007).

In addition to treating organ-confined prostate tumors (i.e., stages T1 and T2), cryoablation is a treatment option for patients with locally invasive stage T3 disease when there is no lymph node involvement. It may also be used as a salvage procedure for patients with residual or recurrent cancer following prostate surgery or radiation therapy in the absence of metastasis. Cryosurgery for the treatment of patients with T4 tumors, as palliation therapy for patients with metastasis, and as salvage therapy following failure of treatments with other than radiation has not been established (American Urological Association, 2010 [AUA]; Finley, et al., 2010; Lam, et al., 2007; Marberger, 2007; National Cancer Institute [NCI], 2006; NCI, 2003; Centers for Medicare and Medicaid Services [CMS], 2001).

U.S. Food and Drug Administration (FDA)

Cryoablation systems are approved by the FDA as 510(k) class II devices. An example is the Cryocare CS Surgical System (Endocare, Inc., Irvine, CA) approved for “use in open, minimally invasive or endoscopic surgical procedures in the areas in general surgery, urology, gynecology, oncology, neurology, dermatology, ENT, proctology, pulmonary surgery and thoracic surgery. The system is designed to freeze/ablate tissue by the application of extreme cold temperatures including prostate and kidney tissue, liver metastases, tumors, skin lesions, and warts” (FDA, 2006).

Literature Review

Systematic reviews (Shelley, et al., 2007; Aus, et al., 2006; Ahmed, et al., 2005), randomized controlled trials (Donnelly, et al., 2010), case series (Ellis, et al., 2007; NG, et al., 2007; Polascik, et al., 2007; Cresswell, et al., 2006; Prepelica, et al., 2005; Chin, et al., 2003), and retrospective reviews (Cohen, et al., 2008; Lambert, et al., 2007; Bahn, et al., 2003) have reported that cryoablation may be beneficial for the treatment of patients with clinically localized prostate cancer, resulting in negative post-treatment prostatic biopsies and low or undetectable serum prostate-specific antigen (PSA) levels. It may also be a viable salvage treatment alternative for patients with recurrent disease only following failed radiotherapy.

There is insufficient evidence to support cryoablation for T4 prostate tumors or as palliation therapy when metastatic disease is present. The effectiveness of cryosurgery as salvage therapy following radical prostatectomy or other non-radiation therapies has not been established. Evidence is primarily in the form of retrospective reviews with small patient populations (Siddiqui, et al., (2007).

Professional Societies/Organizations

American Cancer Society (ACS): The ACS (2010) states that cryosurgery may be a treatment option for localized cancer if the prostate gland is not enlarged. Cryotherapy offers a minimally invasive approach, with less blood loss, shorter hospital stay, less pain, and shorter recovery time. They also noted that less is known about the long-term effectiveness of cryosurgery compared to radiation and surgery. For this reason, it is offered as a treatment option to fewer patients. Cryotherapy may be used to treat patients who experience recurrent carcinoma if the disease is still localized.

American College of Radiology (ACR): in a 2006 guideline on the treatment of locally advanced, (high-risk) prostate cancer, ACR stated that studies reporting on the use of cryosurgery for the treatment of high-risk patients with long-term follow-up are few in number, and “high-level evidence with appropriate follow-up continues to be lacking” (Lee, et al., 2006).

American Urological Association (AUA): In their 2008 (validated 2010) best practice policy statement on cryosurgery for the treatment of localized prostate cancer, the AUA stated that primary cryosurgery is a treatment option in men with “clinically organ-confined disease of any grade with a negative metastatic evaluation. High-risk patients may require multi-modal therapy”. Due to the limited data, AUA noted that the

outcomes in men with clinical T3 disease treated with cryosurgery are undetermined. The Panel also stated that “salvage cryosurgery can be considered as a treatment option for curative intent in men who have failed radiation therapy”.

European Association of Urology (EAU): In their guidelines on prostate cancer, the EAU (2010) stated that the ideal candidates for cryosurgery are those with organ-confined carcinoma and those with minimal tumor extension beyond the prostate, a prostate size ≤ 40 milliliters (mL), a PSA less than 20 nanograms (ng)/mL, and a Gleason score of less than seven. They also noted that since there are limited long-term outcome data, patients with a life expectancy of more than ten years should be informed accordingly. The EAU listed cryotherapy as a treatment option for the management of patients who demonstrate PSA failure following radiation therapy, but noted that there are limited studies and “results are not very promising”.

National Cancer Institute (NCI): According to NCI (2010, 2006, 2003), cryosurgery is a treatment option for early-prostate cancer that is localized to the prostate gland, but it is not used to treat prostate cancer that has metastasized. It is often used for more advanced, confined cancer when surgery isn’t an option. NCI also stated that “cryosurgery is less well established than standard prostatectomy, and long-term outcomes are not as well established as with prostatectomy or radiation therapy. Serious toxic effects include bladder outlet injury, urinary incontinence, sexual impotence, and rectal injury.

National Comprehensive Cancer Network (NCCN): In their discussion of the treatment of recurrence of prostate cancer following radiation therapy, NCCN (2010) states that local interventions (such as salvage prostatectomy, cryotherapy and brachytherapy) are a treatment option for patients with a positive biopsy with low suspicion of metastases and should be based upon “the patient’s risk of progression, likelihood of success, and the risks involved with the therapy”.

National Institute for Health and Clinical Excellence (NICE): NICE (United Kingdom) published two 2005 interventional procedure guidelines on the use of cryotherapy for the treatment of prostate cancer. They stated that the current evidence supports the use of cryotherapy as a primary treatment for prostate cancer and as a treatment for recurrent prostate cancer. It may be used as a primary treatment for patients with “localized or locally advanced prostate cancer” (NICE, 2005a). Cryotherapy may be used for recurrent cancer that has been “refractory to other treatments, such as radiotherapy or hormone therapy” (NICE, 2005b). However, in the 2008 guidance on the diagnosis and treatment of prostate cancer, NICE stated that due to a lack of evidence on quality of life benefits and long-term survival, cryosurgery was not recommended for routine use.

Summary

Professional societies and evidence in the published peer-reviewed scientific literature support the safety and effectiveness of cryoablation as a primary treatment option for individuals with clinically localized, stage T1-T3 prostate cancer without lymph node involvement. In the absence of metastasis, cryoablation is also considered a salvage treatment for individuals with residual or recurrent cancer following radiation therapy.

Evidence in the published, peer-reviewed scientific literature does not support cryoablation for the treatment of prostate cancer for any other indication (e.g., salvage therapy for recurrent cancer following failure of therapy other than radiation, individuals with T4 tumors, or as palliation therapy for individuals with metastatic disease). Studies are primarily in the form of case series and retrospective reviews with small patient populations. The clinical benefit of cryosurgery in these patients has not been established.

Coding/Billing Information

Note: This list of codes may not be all-inclusive.

Covered when medically necessary:

CPT®* Codes	Description
55873	Cryosurgical ablation of the prostate (includes ultrasonic guidance for interstitial cryosurgical probe placement)

ICD-9-CM Diagnosis Codes	Description
185	Malignant neoplasm of the prostate
198.82	Secondary malignant neoplasm of genital organs
233.4	Carcinoma in situ prostate

***Current Procedural Terminology (CPT®) © 2010 American Medical Association: Chicago, IL.**

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Policy History

Pre-Merger Organizations	Last Review Date	Policy Number	Title
CIGNA HealthCare	10/15/2007	0199	Cryoablation for Prostate Cancer
Great-West Healthcare	09/19/2007	95.309.05	Cryoablation for Prostate Cancer

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Connecticut General Life Insurance Company has acquired the business of Great-West Healthcare from Great-West Life & Annuity Insurance Company (GWLA). Certain products continue to be provided by GWLA (Life, Accident and Disability, and Excess Loss). GWLA is not licensed to do business in New York. In New York, these products are sold by GWLA's subsidiary, First Great-West Life & Annuity Insurance Company, White Plains, N.Y.