

Corporate Medical Policy

Whole Gland Ablative Treatments of Prostate Cancer

File Name: whole_gland_ablative_treatments_of_prostate_cancer

Origination: 3/1997

Last Review: 4/2023

Description of Procedure or Service

Prostate cancer is the most commonly diagnosed cancer in men and the second leading cause of cancer death among men in the United States, with an estimated 268,490 new cases and 34,500 deaths in 2022. The diagnosis and grading of prostate cancer are performed by taking a biopsy of the prostate gland. Options for treatment include cryoablation and high-intensity focused ultrasound (HIFU), as well as other ablative therapies.

Cryoablation, also known as cryotherapy or cryosurgery, is a procedure that attacks cancer cells using extremely cold gas. This technique can be used to treat prostate cancer by percutaneously inserting thin, needle-like cryoprobes into the prostate gland and then sending very cold gas down the cryoprobes to rapidly freeze and thaw the tissue, causing necrosis. This review evaluates evidence on the use of total (whole gland, definitive therapy) cryoablation. Subtotal (focal) cryoablation and alternative procedures are considered in the policy titled Focal Treatments for Prostate Cancer.

Whole gland ablative therapy is one of several methods available to treat clinically localized prostate cancer and may be considered an alternative to radical prostatectomy or external-beam radiotherapy. It also may be used for salvage of non-metastatic relapse following initial therapy for clinically localized disease. Cryosurgical ablation is less invasive than radical prostatectomy and recovery time may be shorter. External beam radiotherapy requires multiple treatments, whereas cryoablation usually requires a single treatment. Options for treatment include cryoablation and high-intensity focused ultrasound (HIFU), as well as other ablative therapies.

HIFU focuses high-energy ultrasound waves on a portion of the prostate at a time and then repeated until the entire prostate may be treated by increasing the temperature at each focus to over 80 degrees C. This causes a discrete locus of coagulative necrosis of approximately 3×3×10 mm. The surgeon uses a transrectal probe to plan, perform, and monitor treatment in a real-time.

Regulatory Status

Cryoablation

Cryoablation of prostate cancer uses previously approved and available cryoablation systems and, as a surgical procedure, is not subject to regulation by the U.S. Food and Drug Administration (FDA). A number of cryoablation systems and cryoprobes have general surgical FDA 510(k) marketing clearance. Examples of cryoablation devices that specifically mention treatment of prostate cancer in their marketing clearance are two Endocare® Inc. devices, Cryocare CS® and Cryocare CN2® systems, and two Galil Medical devices, Visual-ICE® Cryoablation System and IceRod® CX Cryoablation Needle.

High-Intensity Focused Ultrasound

In 2015, the Sonablate® 450 (SonaCare Medical) was approved by FDA through a de novo request and classified the device as class II under the generic name “high intensity ultrasound system for prostate tissue ablation”. This device was the first of its kind to be approved in the United States. In November 2015, Ablatherm®-HIFU (EDAP TMS) was cleared for marketing by the FDA through the 510(k)

Whole Gland Ablative Treatments of Prostate Cancer

process. In June 2018, EDAP received 510(k) clearance for its Focal-One® HIFU device designed for prostate tissue ablation procedures. This device fuses magnetic resonance and 3D biopsy data with real-time ultrasound imaging, allowing urologists to view detailed images of the prostate on a large monitor and direct high-intensity ultrasound waves to ablate the targeted area.

Related Policies

Focal Treatments for Prostate Cancer

Radiosurgery, Stereotactic Approach

Intensity-Modulated Radiation Therapy (IMRT) of the Prostate

*****Note: This Medical Policy is complex and technical. For questions concerning the technical language and/or specific clinical indications for its use, please consult your physician.**

Policy

BCBSNC will provide coverage for Whole Gland Ablative Treatments of Prostate Cancer by Cryoablation or HIFU when it is determined to be medically necessary because the medical criteria and guidelines shown below are met.

Benefits Application

This medical policy relates only to the services or supplies described herein. Please refer to the Member's Benefit Booklet for availability of benefits. Member's benefits may vary according to benefit design; therefore member benefit language should be reviewed before applying the terms of this medical policy.

When Whole Gland Ablative Treatments of Prostate Cancer are covered

Whole gland cryoablation of the prostate may be considered medically necessary as treatment of clinically localized (organ-confined) prostate cancer when performed

- As initial treatment, or
- As salvage treatment of disease that recurs following radiotherapy.

High-intensity focused ultrasound (HIFU) may be considered medically necessary to treat 1) Recurrent prostate cancer after radiation; or 2) Primary or initial, previously untreated, prostate cancer in the setting of prior pelvic radiation to treat another condition, when **ALL** of the following criteria are met:

1. Disease recurrence is localized, without evidence of distant metastases or nodal involvement, AND
2. HIFU therapy is being given with curative intent, AND
3. Current PSA is < 10ng/mL, AND
4. The original disease (pre-radiation therapy) was stage T1-T2, NX or N0, OR is in the setting or prior pelvic radiation AND
5. The risks and benefits of the different modalities for therapy of localized, radio-recurrent prostate cancer or treatment options for initial prostate cancer in the setting of prior pelvic radiation have been discussed, and it has been determined that HIFU is the best treatment choice for the patient.

When Whole Gland Ablative Treatments of Prostate Cancer are not covered

All other treatment modalities for whole gland ablation of prostate cancer are considered investigational.

Policy Guidelines

Whole Gland Ablative Treatments of Prostate Cancer

For individuals who are considering initial treatment for localized prostate cancer who receive whole gland cryoablation, the evidence includes systematic reviews, two randomized controlled trials, and many comparative and noncomparative observational studies. Relevant outcomes are overall survival, disease-specific survival, symptoms, functional outcomes, quality of life, and treatment-related morbidity. High-quality data comparing cryoablation with external beam radiotherapy (EBRT), radical prostatectomy, or active surveillance are lacking, but available data have suggested similar overall survival and disease-specific survival rates compared with radical prostatectomy and EBRT. The evidence is sufficient to determine that the technology results in an improvement in the net health outcome.

For individuals who have salvage treatment for a recurrence of localized prostate cancer following radiotherapy who receive whole gland cryoablation, the evidence primarily includes case series and a few retrospective studies comparing salvage cryoablation with salvage prostatectomy or brachytherapy. Relevant outcomes are overall survival, disease-specific survival, symptoms, functional outcomes, quality of life, and treatment-related morbidity. High-quality data comparing salvage cryoablation with salvage prostatectomy or brachytherapy are lacking, though limited evidence suggests that salvage cryotherapy may be associated with better survival outcomes than prostatectomy. Men with recurrent localized prostate cancer have limited treatment options and prostatectomy can be difficult in tissue that has been irradiated. The evidence is sufficient to determine that the technology results in an improvement in the net health outcome.

For individuals who have localized, radiorecurrent prostate cancer who receive HIFU, the evidence includes case series and systematic reviews of these series. Relevant outcomes are overall and disease-specific survival, symptoms, change in disease status, functional outcomes, quality of life, and treatment-related morbidity. Systematic reviews have reported that with salvage focal therapies, HIFU has lower rates of local tumor control and higher rates of incontinence, as compared to brachytherapy and cryotherapy. However, overall oncologic outcomes with use of HIFU are acceptable, and individual patient and disease characteristics should be taken into consideration when choosing the treatment modality that will most benefit the patient. The evidence is sufficient to determine that the technology results in an improvement in the net health outcome.

There is extremely limited data to determine the best approaches to treat initial prostate cancer when the patient has already received prior pelvic radiation to treat a different condition. However, the same relative contraindications exist for consideration of prostatectomy or additional radiation. Therefore, the scenario of prior pelvic radiation is considered similar to the scenario of prior prostate radiation for the applicability of ablative treatment with cryoablation or HIFU.

National Comprehensive Cancer Network

The National Comprehensive Cancer Network (NCCN) guidelines (v.4 2022) for prostate cancer indicate cryosurgery and high-intensity focused ultrasound are options for radiotherapy recurrence in patients who have no evidence of metastatic disease. NCCN does not recommend cryotherapy as routine primary therapy for localized prostate cancer due to limited data comparing cryotherapy with radiation or radical prostatectomy.

Billing/Coding/Physician Documentation Information

This policy may apply to the following codes. Inclusion of a code in this section does not guarantee that it will be reimbursed. For further information on reimbursement guidelines, please see Administrative

Whole Gland Ablative Treatments of Prostate Cancer

Policies on the Blue Cross Blue Shield of North Carolina web site at www.bcbsnc.com. They are listed in the Category Search on the Medical Policy search page.

Applicable codes: 55873 and 55880

BCBSNC may request medical records for determination of medical necessity. When medical records are requested, letters of support and/or explanation are often useful, but are not sufficient documentation unless all specific information needed to make a medical necessity determination is included.

Scientific Background and Reference Sources

For Evidence Based Guideline titled Cryosurgery Ablation of the Prostate

Urological Consultant Review, 10/93

ECRI Executive Briefings - No. 65 - 1/98

Medical Policy Advisory Group Review, 3/99

Specialty Matched Consultant Advisory Panel - 5/2001

BCBSA Medical Policy Reference Manual, 8/15/01; 7.01.79

ECRI Hotline Response: Cryosurgery for Prostate Cancer. Accessed 4/24/2003

Specialty Matched Consultant Advisory Panel - 5/2003

Interventional procedures overview of salvage cryotherapy for recurrent prostate cancer. IP overview: Salvage cryotherapy for recurrent prostate cancer. National Institute for Clinical Excellence (NICE). [6/2004]. Retrieved on 3/29/05 from <http://www.nice.org.uk/pdf/ip/ip130overview.pdf>

ECRI Hotline Response - Cryosurgery for Prostate Cancer (Update of full TA Report) (09/01/2004) retrieved on 3/29/05 from http://www.ta.ecri.org/Hotline/Prod/summary/detail.aspx?doc_id+7408&q=prostate&anm

BCBSA Medical Policy Reference Manual [Electronic Version]. 7.01.79, 11/9/04.

Specialty Matched Consultant Advisory Panel - 5/2005

For Evidence Based Guideline re-titled Cryoablation of Prostate Cancer

Chou R, Dana T, Bougatsos C et al. Treatments for Localized Prostate Cancer: Systematic Review to Update the 2002 U.S. Preventive Services Task Force Recommendation. Rockville (MD)2011. Retrieved from <http://www.ncbi.nlm.nih.gov/books/NBK82315/>

National Cooperative Cancer Network. Prostate cancer. Clinical Practice Guidelines in Oncology, v.2.2013. Retrieved from http://www.nccn.org/professionals/physician_gls/pdf/prostate.pdf.

American Urological Association Education and Research, Inc. Best practice policy statement on cryosurgery for the treatment of localized prostate cancer. American Urological Association Education and Research, Inc. Linthicum (MD):2008. 50 p. Retrieved from <http://www.auanet.org/content/media/cryosurgery08.pdf>

BCBSA Medical Policy Reference Manual [Electronic Version]. 7.01.79, 5/10/12

Whole Gland Ablative Treatments of Prostate Cancer

Specialty Matched Consultant Advisory Panel review – 11/2012

BCBSA Medical Policy Reference Manual [Electronic Version]. 7.01.79, 5/9/13

Specialty Matched Consultant Advisory Panel review – 11/2013

National Cooperative Cancer Network. Prostate cancer. Clinical Practice Guidelines in Oncology, v.2.2014. http://www.nccn.org/professionals/physician_gls/pdf/prostate.pdf.

Best practice policy statement on cryosurgery for the treatment of localized prostate cancer. Linthicum (MD): American Urological Association Education and Research, Inc.; 2008. 50 p. <http://www.auanet.org/education/guidelines/cryosurgery.cfm>

BCBSA Medical Policy Reference Manual [Electronic Version]. 7.01.79, 5/22/14

Specialty Matched Consultant Advisory Panel review – 11/2014

For Corporate Medical Policy re-titled Whole Gland Ablative Treatment of Prostate Cancer

BCBSA Medical Policy Reference Manual [Electronic Version]. 7.01.79, 8/12/21
American Urological Association (AUA). Clinically Localized Prostate Cancer: AUA/ASTRO/SUO Guideline. 2022;
<https://www.auanet.org/documents/Guidelines/PDF/Localized%20Prostate%20Cancer%20Guideline%20050922.pdf>

Specialty Matched Consultant Advisory Panel review – 11/2022

Medical Director review

Policy Implementation/Update Information

For Evidence Based Guideline titled Cryosurgery Ablation of the Prostate

- 10/93 Original policy issued
- 3/96 Reviewed: Remains investigational
- 3/97 Reaffirmed
- 3/99 Reaffirmed
- 7/99 Reformatted, Description of Procedure or Service changed, Medical Term Definitions added.
- 11/99 Revised. Available for coverage for certain indications.
- 12/00 New 2001 CPT added; 55873. Coding system changes.
- 5/01 Specialty Matched Consultant Advisory Panel review (5/2001). Removed local failure after radical prostatectomy as a covered indication.
- 12/01 Implementation information from 5/01 corrected. Removal of "local failure after radical prostatectomy" was removed from "When Cryosurgery Ablation of the Prostate is Not Covered" section of policy.
- 6/03 Specialty Matched Consultant Advisory Panel review (5/23/03). No change to criteria. Revised Description section for clarity. Removed codes G0160 and G0161 from Billing/Coding section. Codes have been deleted from HCPCS. Benefits Application section revised.
- 3/04 Billing/Coding section updated for consistency.

Whole Gland Ablative Treatments of Prostate Cancer

6/2/05 Specialty Matched Consultant Advisory Panel review 5/23/05. Description section revised. Under "When Covered" section added salvage cryosurgery of the prostate for recurrent cancer as covered for patients with localized disease who have failed a trial of radiation therapy as their primary treatment and meet one of the following conditions: Stage T2B or below, Gleason score less than 9, PSA less than 8 ng/mL. Under "When not Covered" removed numbers 2 & 3 and incorporated number 1 into the first sentence. Policy status changed to "Active policy, no longer scheduled for routine literature review." Notice given 6/2/05. Effective date 8/4/05.

8/28/06 Medical Policy changed to Evidence Based Guideline. (pmo)

6/22/10 Policy Guideline Number(s) removed (amw)

For Evidence Based Guideline re-titled Cryoablation of Prostate Cancer

1/15/13 Evidence Based Guideline re-titled from "Cryosurgery Ablation of the Prostate" to "Cryoablation of Prostate Cancer." Status changed to active. Guideline will undergo routine review. Description section updated. Added "Related Policies" to Description section. "When Recommended" section revised to state: "Cryoablation of the prostate is recommended as treatment of clinically localized (organ-confined) prostate cancer when performed: 1) as initial treatment or 2) as salvage treatment of disease that recurs following radiation therapy." "When not Recommended" section revised to state: "Subtotal prostate cryoablation is not recommended in the treatment of prostate cancer." Medical Director review 11/2012. Specialty Matched Consultant Advisory Panel review 11/2012. References updated. (mco)

6/11/13 References updated. (mco)

12/10/13 Medical Director review 11/2013. Specialty Matched Consultant Advisory Panel review 11/2013. No changes to Guideline Statements. (mco)

7/15/14 Description section updated. References updated. No changes to Guideline Statements. (mco)

12/9/14 Related policies added. Specialty Matched Consultant Advisory Panel review 11/24/2014. No changes to Guideline Statements. (sk)

7/1/15 Medical Director review. Policy archived. (sk)

For Corporate Medical Policy re-titled Whole Gland Ablative Treatment of Prostate Cancer

2/8/22 Medical Director review. Reference added. Policy updated and returned to active review. Policy statement updated to include both cryoablation and high intensity focused ultrasound as covered when criteria are met. (sk)

5/2/23 Policy review. Reference added. NCCN guideline updated. Specialty Matched Consultant Advisory Panel review 11/16/2022. Description section updated. When Covered statement updated to include criteria for whole gland cryoablation for initial treatment. When Covered statement for whole gland high intensity focused ultrasound unchanged. Policy Guidelines updated. Medical Director review. (sk)

Medical policy is not an authorization, certification, explanation of benefits or a contract. Benefits and eligibility are determined before medical guidelines and payment guidelines are applied. Benefits are determined by the group contract and subscriber certificate that is in effect at the time services are rendered. This document is solely provided for informational purposes only and is based on research of current medical literature and review of common medical practices in the treatment and diagnosis of disease. Medical practices and knowledge are constantly changing and BCBSNC reserves the right to review and revise its medical policies periodically.