Whole Gland Cryoablation of Prostate Cancer

Policy # 00022
Original Effective Date: 06/24/2002
Current Effective Date: 05/13/2024

Applies to all products administered or underwritten by Blue Cross and Blue Shield of Louisiana and its subsidiary, HMO Louisiana, Inc. (collectively referred to as the "Company"), unless otherwise provided in the applicable contract. Medical technology is constantly evolving, and we reserve the right to review and update Medical Policy periodically.

Note: Focal Treatments for Prostate Cancer are addressed separately in medical policy 00484.

Note: Stereotactic Radiosurgery and Stereotactic Body Radiation Therapy are addressed separately in medical policy 00045.

Note: Proton Beam Therapy are addressed separately in medical policy 00187.

When Services May Be Eligible for Coverage

Coverage for eligible medical treatments or procedures, drugs, devices or biological products may be provided only if:

- *Benefits are available in the member's contract/certificate, and*
- *Medical necessity criteria and guidelines are met.*

Based on review of available data, the Company may consider whole gland cryoablation of the prostate as treatment of clinically localized (organ-confined) prostate cancer when patient selection criteria are met to be **eligible for coverage.****

Patient Selection Criteria

Coverage eligibility for whole gland cryoablation of the prostate as treatment of clinically localized (organ-confined) prostate cancer will be considered when any of the following criteria are met:

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

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When Services Are Considered Investigational

Coverage is not available for investigational medical treatments or procedures, drugs, devices or biological products.

Based on review of available data, the Company considers the use of whole gland cryoablation of the prostate as treatment of clinically localized (organ-confined) prostate cancer when patient selection criteria are not met to be **investigational.***

Background/Overview

Prostate Cancer

Prostate cancer is the most commonly diagnosed cancer in men and the second leading cause of cancer death among men in the U. S., with an estimated 288,300 new cases and 34,700 deaths in 2023. The diagnosis and grading of prostate cancer are performed by taking a biopsy of the prostate gland.

Treatment

Whole gland (also known as total) cryoablation is one of several methods used to treat clinically localized prostate cancer and may be considered an alternative to radical prostatectomy or external-beam radiotherapy (EBRT). Additionally, whole gland cryoablation may be used for salvage of nonmetastatic relapse following initial therapy for clinically localized disease. Using percutaneously inserted cryoprobes, the glandular tissue is rapidly frozen and thawed to cause tissue necrosis. 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.

FDA or Other Governmental Regulatory Approval

U.S. Food and Drug Administration (FDA)

Cryoablation of prostate cancer is a surgical procedure that uses previously approved and available cryoablation systems; and as a surgical procedure, it is not subject to regulation by the U.S. FDA.

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Rationale/Source

This medical policy was developed through consideration of peer-reviewed medical literature generally recognized by the relevant medical community, U.S. FDA approval status, nationally accepted standards of medical practice and accepted standards of medical practice in this community, technology evaluation centers, reference to federal regulations, other plan medical policies, and accredited national guidelines.

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.

Summary of Evidence

For individuals who are considering initial treatment for localized prostate cancer who receive whole gland cryoablation, the evidence includes systematic reviews, 2 randomized controlled trials, and many comparative and noncomparative observational studies. Relevant outcomes are overall survival (OS), disease-specific survival, symptoms, functional outcomes, quality of life (QOL), 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 OS 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 OS, disease-specific survival, symptoms, functional outcomes, QOL, 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.

Additional Information
Input was received from 1 physician specialty society and 4 academic medical centers while this policy was under review in 2009. There was strong agreement that cryoablation should be considered medically necessary as an option in the initial treatment of organ-confined prostate cancer, as well as for use as salvage therapy for disease recurrence after radiotherapy.

Supplemental Information

Clinical Input From Physician Specialty Societies and Academic Medical Centers
In response to requests, input was received from 1 physician specialty society and 4 academic medical centers while this policy was under review in 2009. There was strong agreement that cryoablation should be considered medically necessary as an option in the initial treatment of organ-confined prostate cancer, as well as for use as salvage therapy for disease recurrence after radiotherapy.

Practice Guidelines and Position Statements
Guidelines or position statements will be considered for inclusion in ‘Supplemental Information' if they were issued by, or jointly by, a US professional society, an international society with US representation, or National Institute for Health and Care Excellence (NICE). Priority will be given to guidelines that are informed by a systematic review, include strength of evidence ratings, and include a description of management of conflict of interest.

National Comprehensive Cancer Network
The National Comprehensive Cancer Network (NCCN) guidelines (v.1 2023) for prostate cancer indicate cryosurgery and high-intensity focused ultrasound are options for radiotherapy recurrence in patients who have no evidence of metastatic disease (Grade 2B). NCCN does not recommend cryotherapy as routine primary therapy for localized prostate cancer due to limited long-term data comparing cryotherapy with radiation or radical prostatectomy.

American Urological Association et al
In 2022, the American Urological Association and the American Society for Radiology Oncology issued a joint, updated guideline on the treatment of clinical localized prostate cancer; the guideline was additionally endorsed by the Society of Urologic Oncology. In the guideline, treatment recommendations are stratified according to risk group, and ablative techniques are discussed in general with no recommendations specific to whole-gland cryoablation (Table 1).

Table 1. Treatment Recommendations Related to Cryoablation by Prostate Cancer Risk Group

Severity/ Risk Group	Risk Definition	Treatment Recommendation	LOE	GOE	Clinical Considerations
Low-risk disease	PSA <10 ng/mL ANDGrade Group 1 AND clinical stage T1-T2a	Forpatientswithlow-riskprostatecancer, clinicianshouldrecommendactive surveillanceasthepreferredmanagement option	Strong	A	The Panel believes that the benefits of aggressive treatment do not outweigh the risk of treatment-related harms for most patients with low-risk disease. The Panel acknowledges that select patients with low-risk disease may elect definitive local therapy after an informed discussion between

					clinician and patient.
Intermediate-risk disease	PSA 10-<20 ng/mL OR Grade Group 2-3 OR clinical stage T2b-c	Clinicians should inform patients with intermediate-risk prostate cancer considering whole gland or focal ablation that there are a lack of high-quality data comparing ablation outcomes to radiation therapy, surgery, and active surveillance	Expert opinion	---	The Panel believes that ablation maybe considered in select, appropriately informed patients (with clinical trial enrollment prioritized). Patients considering ablation should be counseled regarding side effects and recurrence risk and should be followed post-ablation with PSA, DRE, MRI, and biopsy tailored to their specific health and cancer characteristics.
High-risk disease	PSA>20 ng/mL OR Grade Group 4-5	Clinicians should not recommend whole gland or focal ablation for patients with high-risk prostate	Expert opinion	---	There is a lack of data supporting treatment of high-risk disease with ablation.

	OR clinical stageT3	cancer outside of a clinical trial			

DRE: digital rectal exam; GOE: grade of evidence; HIFU: high-intensity focused ultrasound; LOE: level of evidence; MRI: magnetic resonance imaging; PSA: prostate-specfic antigen.

U.S. Preventive Services Task Force Recommendations

A systematic review of localized prostate cancer treatments was prepared by Fenton et al (2018) for the Agency for Healthcare Research and Quality, updating the 2002 U.S. Preventive Services Task Force recommendation. Reviewers found no studies comparing cryoablation with watchful waiting and no randomized trials or cohort studies evaluating overall survival or prostate cancer-specific mortality outcomes. The available evidence was mostly from uncontrolled studies, found to be very limited, and not sufficiently reliable to estimate the benefits or harms of cryoablation.

Medicare National Coverage

The Centers for Medicare & Medicaid Services have determined that total cryotherapy is medically necessary and appropriate as primary treatment for clinically localized prostate cancer in stages T1 to T3. Salvage cryoablation is only medically necessary and appropriate in localized disease when radiotherapy has failed as primary treatment, and the patient meets 1 of 3 criteria: stage T2B or below, Gleason score less than 9, or prostate-specific antigen level of less than 8 ng/mL. Salvage cryoablation after the failure of other therapies is not covered.

Ongoing and Unpublished Clinical Trials

Some currently ongoing and unpublished trials that might influence this review are listed in Table 2.

Table 2. Summary of Key Trials

NCT No.	Trial Name	Planned Enrollment	Completion Date
Ongoing			
NCT01727284	Technical Success, Safety, and Short and Long-Term Efficacy for MR-Guided Cryoablation of Prostate Bed Recurrences	100	Dec 2023

NCT04891536	Salvage Cryotherapy for Recurrent Prostate Cancer After Radiation Therapy (CRIOAND2021)	100	May 2026
Unpublished			
NCT01398657	Cryotherapy With or Without Short-term Adjuvant Androgen-Deprivation Therapy for High-Risk Localized Prostate Cancer - Open-Label Randomized Clinical Study	182	Jun 2016 (unknown; last updated Nov 2012)
NCT02615223	A Prospective Multi-Center Study to Compare the QOL and Efficacy of Endocrine Therapy with or without Cryoablation for Stage IV Prostate Cancer	120	Dec 2018 (unknown; last updated Jun 2017)
NCT02605226	A Prospective Multi-Center Study to Compare the QOL and Efficacy of External Beam Radiation Therapy or Cryoablation Therapy for Stage III Prostate Cancer (CRYO-PCA-III)	240	Dec 2018 (unknown; last updated Jun 2017)
NCT03348722	START (Active Surveillance or Radical Treatment for Newly Diagnosed Patients with a Localized, Low Risk, Prostate Cancer): an Epidemiological Study of the Oncology Network of Piemonte and Valle d'Asosta, Italy	3000	Nov 2019 (unknown; last updated Nov 2017)

NCT: national clinical trial.

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Policy History

Original Effective Date: 06/24/2002
Current Effective Date: 05/13/2024

06/20/2002	Medical Policy Committee review
06/24/2002	Managed Care Advisory Council approval. Format revision. No substance change to policy.
08/31/2004	Medical Director review
09/21/2004	Medical Policy Committee review. Format revision. No substance change to policy.
09/27/2004	Managed Care Advisory Council approval
09/07/2005	Medical Director review
09/20/2005	Medical Policy Committee review. Format revision. Coverage eligibility unchanged. The following clarification statement was added: “Based on review of available data, the Company considers other uses of cryoablation of the prostate to be investigational.”
09/22/2005	Quality Care Advisory Council approval
07/07/2006	Format revision, including addition of FDA and or other governmental regulatory approval and rationale/source. Coverage eligibility unchanged.
10/04/2006	Medical Director review

10/18/2006	Medical Policy Committee approval. Format revision, including addition of information added to FDA and or other governmental regulatory approval. References updated and additional references added. Coverage eligibility unchanged.
11/07/2007	Medical Director review
11/15/2007	Medical Policy Committee approval. No change to coverage eligibility.
11/05/2008	Medical Director review
11/18/2008	Medical Policy Committee approval. No change to coverage eligibility. Rationale updated.
05/07/2009	Medical Director review
05/20/2009	Medical Policy Committee approval. Revised two criteria bullets in coverage section as follows: • "As an initial treatment of clinically localized (organ-confined) primary prostate cancer; or • As salvage treatment of recurrent (following radiation therapy) localized prostate cancer." Added investigational statement as follows, "Based on review of available data, the Company considers subtotal prostate cryoablation in the treatment of prostate cancer to be investigational.*"
06/03/2010	Medical Policy Committee review
06/16/2010	Medical Policy Implementation Committee approval
05/05/2011	Medical Policy Committee review
05/18/2011	Medical Policy Implementation Committee approval. No change.
05/03/2012	Medical Policy Committee review
05/16/2012	Medical Policy Implementation Committee approval. No change to coverage.
06/06/2013	Medical Policy Committee review
06/25/2013	Medical Policy Implementation Committee approval. No change to coverage.
06/05/2014	Medical Policy Committee review
06/18/2014	Medical Policy Implementation Committee approval. No change to coverage. Added FDA section.
08/03/2015	Coding update: ICD10 Diagnosis code section added; ICD9 Procedure code section removed.
09/03/2015	Medical Policy Committee review
09/23/2015	Medical Policy Implementation Committee approval. No change to coverage.
11/03/2016	Medical Policy Committee review

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11/16/2016	Medical Policy Implementation Committee approval. Title change, policy statements adjusted to address whole gland treatment.
01/01/2017	Coding update: Removing ICD-9 Diagnosis Codes
11/02/2017	Medical Policy Committee review
11/15/2017	Medical Policy Implementation Committee approval. No change to coverage.
11/08/2018	Medical Policy Committee review
11/21/2018	Medical Policy Implementation Committee approval. No change to coverage.
11/07/2019	Medical Policy Committee review
11/13/2019	Medical Policy Implementation Committee approval. No change to coverage.
04/02/2020	Medical Policy Committee review
04/08/2020	Medical Policy Implementation Committee approval. No change to coverage.
04/01/2021	Medical Policy Committee review
04/14/2021	Medical Policy Implementation Committee approval. No change to coverage.
04/07/2022	Medical Policy Committee review
04/13/2022	Medical Policy Implementation Committee approval. No change to coverage.
04/06/2023	Medical Policy Committee review
04/12/2023	Medical Policy Implementation Committee approval. No change to coverage.
04/04/2024	Medical Policy Committee review
04/10/2024	Medical Policy Implementation Committee approval. No change to coverage.

Next Scheduled Review Date: 04/2025

Coding

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Codes used to identify services associated with this policy may include (but may not be limited to) the following:

Code Type	Code
CPT	55873
HCPCS	C2618
ICD-10 Diagnosis	All related diagnoses

*Investigational – A medical treatment, procedure, drug, device, or biological product is Investigational if the effectiveness has not been clearly tested and it has not been incorporated into standard medical practice. Any determination we make that a medical treatment, procedure, drug, device, or biological product is Investigational will be based on a consideration of the following:

A. Whether the medical treatment, procedure, drug, device, or biological product can be lawfully marketed without approval of the U.S. Food and Drug Administration (FDA) and whether such approval has been granted at the time the medical treatment, procedure, drug, device, or biological product is sought to be furnished; or
B. Whether the medical treatment, procedure, drug, device, or biological product requires further studies or clinical trials to determine its maximum tolerated dose, toxicity, safety, effectiveness, or effectiveness as compared with the standard means of treatment or diagnosis, must improve health outcomes, according to the consensus of opinion among experts as shown by reliable evidence, including:
    1. Consultation with technology evaluation center(s);
    2. Credible scientific evidence published in peer-reviewed medical literature generally recognized by the relevant medical community; or

3. Reference to federal regulations.

**Medically Necessary (or "Medical Necessity") - Health care services, treatment, procedures, equipment, drugs, devices, items or supplies that a Provider, exercising prudent clinical judgment, would provide to a patient for the purpose of preventing, evaluating, diagnosing or treating an illness, injury, disease or its symptoms, and that are:

A. In accordance with nationally accepted standards of medical practice;
B. Clinically appropriate, in terms of type, frequency, extent, level of care, site and duration, and considered effective for the patient's illness, injury or disease; and
C. Not primarily for the personal comfort or convenience of the patient, physician or other health care provider, and not more costly than an alternative service or sequence of services at least as likely to produce equivalent therapeutic or diagnostic results as to the diagnosis or treatment of that patient's illness, injury or disease.

For these purposes, "nationally accepted standards of medical practice" means standards that are based on credible scientific evidence published in peer-reviewed medical literature generally recognized by the relevant medical community, Physician Specialty Society recommendations and the views of Physicians practicing in relevant clinical areas and any other relevant factors.

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NOTICE: If the Patient's health insurance contract contains language that differs from the BCBSLA Medical Policy definition noted above, the definition in the health insurance contract will be relied upon for specific coverage determinations.

NOTICE: Medical Policies are scientific based opinions, provided solely for coverage and informational purposes. Medical Policies should not be construed to suggest that the Company recommends, advocates, requires, encourages, or discourages any particular treatment, procedure, or service, or any particular course of treatment, procedure, or service.

NOTICE: Federal and State law, as well as contract language, including definitions and specific contract provisions/exclusions, take precedence over Medical Policy and must be considered first in determining eligibility for coverage.