



Louisiana

Whole Gland Cryoablation of Prostate Cancer

Policy # 00022

Original Effective Date: 06/24/2002

Current Effective Date: 05/11/2020

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 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.

When Services Are Considered Investigational

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

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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 and the third leading cause of cancer deaths among men in the U. S., with an estimated 161360 new cases and 26730 deaths in 2017. 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. 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. Food and Drug Administration.

Rationale/Source

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.

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For individuals who are considering initial treatment for localized prostate cancer who receive whole gland cryoablation, the evidence includes several systematic reviews, two randomized controlled trials, and many comparative and noncomparative observational studies. The 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, 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 external-beam radiotherapy. The evidence is sufficient to determine that the technology results in a meaningful 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 includes primarily noncomparative case series and a few retrospective studies comparing salvage cryoablation with salvage prostatectomy. The relevant outcomes are overall survival, disease-specific survival, symptoms, functional outcomes, quality of life, and treatment-related morbidity. High-quality data comparing cryoablation with prostatectomy was mixed, and evidence comparing cryotherapy with brachytherapy is lacking. Men in this group have few options and prostatectomy can be difficult in tissue that has been irradiated. The evidence is sufficient to determine that the technology results in a meaningful improvement in the net health outcome.

Supplemental Information

Clinical Input From Physician Specialty Societies and Academic Medical Centers

While the various physician specialty societies and academic medical centers may collaborate with and make recommendations during this process, through the provision of appropriate reviewers, input received does not represent an endorsement or position statement by the physician specialty societies or academic medical centers, unless otherwise noted.

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.

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Practice Guidelines and Position Statements

National Comprehensive Cancer Network

The National Comprehensive Cancer Network guidelines (v.2.2019) for prostate cancer indicate cryosurgery and high-intensity focused ultrasound are options for radiotherapy recurrence in patients who have no evidence of metastatic disease.

American Urological Association et al

The American Urological Association, the American Society for Therapeutic Radiology and Oncology, and Society of Urologic Oncology (2017) jointly issued guidelines on clinically localized prostate cancer. Table 1 provides the guideline recommendations for cryosurgery by severity and risk group and Table 2 the clinical guidance specific to cryosurgery.

Table 1. Cryosurgery Recommendations by Prostate Cancer Severity and Risk Group

Severity/Risk Group	Recommendation	LOE	GOE
Very low/low-risk disease	Clinicians should inform low-risk prostate cancer patients considering whole gland cryosurgery that consequent side effects are considerable and survival benefit has not been shown in comparison to active surveillance.	Conditional	C
Intermediate-risk disease	In select patients with intermediate-risk localized prostate cancer, clinicians may consider other treatment options such as cryosurgery.	Conditional	C

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High-risk disease	Cryosurgery, focal therapy, and HIFU treatments are not recommended for men with high-risk localized prostate cancer outside of a clinical trial	Expert opinion	
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GOE: grade of evidence; HIFU: high-intensity focused ultrasound; LOE: level of evidence.

Table 2. Recommendations Related to Cryosurgery

Recommendation	LOE	GOE
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	
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	C
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	
For whole gland cryosurgery treatment, clinicians should utilize a third or higher generation, argon-based cryosurgical system for whole gland cryosurgery treatment.	Clinical principle	

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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	
Clinicians should inform localized prostate cancer patients considering whole gland cryosurgery that erectile dysfunction is an expected outcome.	Clinical principle	
Clinicians should inform localized prostate cancer patients considering whole gland cryosurgery about the adverse events of urinary incontinence, irritative and obstructive urinary problems.	Strong	B

ADT: androgen deprivation therapy; GOE: grade of evidence; LOE: level of evidence.

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 and 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 one of three 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.

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Ongoing and Unpublished Clinical Trials

Some currently ongoing and unpublished trials that might influence this review are listed in Table 3.

Table 3. Summary of Key Trials

NCT No.	Trial Name	Planned Enrollment	Completion Date
<i>Ongoing</i>			
NCT00774436	A Phase II Study of Focal Cryoablation in Low-Risk Prostate Cancer	50	Oct 2018
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
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

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NCT02459912	Unilateral Nerve-Sparing Cryoablation for Low-Risk, Clinically-Localized, Unilateral Prostate Cancer (POTENT-C)	86	Sep 2019
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
NCT03492424	Outcomes of Focal Therapies for Prostate Cancer	200	Mar 2020
NCT01727284	Technical Success, Safety, and Short and Long-Term Efficacy for MR-Guided Cryoablation of Prostate Bed Recurrences	100	Jan 2022
<i>Unpublished</i>			
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)

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NCT: national clinical trial.

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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

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- 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
- 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.

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Louisiana

Whole Gland Cryoablation of Prostate Cancer

Policy # 00022

Original Effective Date: 06/24/2002

Current Effective Date: 05/11/2020

04/02/2020 Medical Policy Committee review

04/08/2020 Medical Policy Implementation Committee approval. No change to coverage.

Next Scheduled Review Date: 04/2021

Coding

The five character codes included in the Blue Cross Blue Shield of Louisiana Medical Policy Coverage Guidelines are obtained from Current Procedural Terminology (CPT®)†, copyright 2019 by the American Medical Association (AMA). CPT is developed by the AMA as a listing of descriptive terms and five character identifying codes and modifiers for reporting medical services and procedures performed by physician.

The responsibility for the content of Blue Cross Blue Shield of Louisiana Medical Policy Coverage Guidelines is with Blue Cross and Blue Shield of Louisiana and no endorsement by the AMA is intended or should be implied. The AMA disclaims responsibility for any consequences or liability attributable or related to any use, nonuse or interpretation of information contained in Blue Cross Blue Shield of Louisiana Medical Policy Coverage Guidelines. Fee schedules, relative value units, conversion factors and/or related components are not assigned by the AMA, are not part of CPT, and the AMA is not recommending their use. The AMA does not directly or indirectly practice medicine or dispense medical services. The AMA assumes no liability for data contained or not contained herein. Any use of CPT outside of Blue Cross Blue Shield of Louisiana Medical Policy Coverage Guidelines should refer to the most current Current Procedural Terminology which contains the complete and most current listing of CPT codes and descriptive terms. Applicable FARS/DFARS apply.

CPT is a registered trademark of the American Medical Association.

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

Code Type	
CPT	55873
HCPCS	C2618
ICD-10 Diagnosis	C61, C79.82, D07.5, Z85.46

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*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 the Blue Cross and Blue Shield Association technology assessment program (TEC) or other nonaffiliated 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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‡ Indicated trademarks are the registered trademarks of their respective owners.

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.

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