Whole Gland Cryoablation of Prostate Cancer

Policy # 00022
Original Effective Date: 06/24/2002
Current Effective Date: 05/10/2021

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 161,360 new cases and 26,730 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. FDA.

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, 2 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, 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. 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.2.2020) 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
In 2017, the American Urological Association, the American Society for Therapeutic Radiology and Oncology, and Society of Urologic Oncology 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	

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
Ongoing			
NCT03492424	Outcomes of Focal Therapies for Prostate Cancer	200	Sep 2025
NCT01727284	Technical Success, Safety, and Short and Long-Term Efficacy for MR-Guided Cryoablation of Prostate Bed Recurrences	100	Dec 2023
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)
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)
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)
NCT00774436	A Phase II Study of Focal Cryoablation in Low-Risk Prostate Cancer	12 (actual)	Jul 2019
NCT02459912	Unilateral Nerve-Sparing Cryoablation for Low-Risk, Clinically-Localized, Unilateral Prostate Cancer (POTENT-C)	86	Sep 2019 (terminated)
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)

NCT: national clinical trial.

References

1. Blue Cross and Blue Shield Association, Medical Policy Reference Manual, "Cryoablation of Prostate Cancer", 7.01.79, 09:2020.

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2. Siegel RL, Miller KD, Jemal A. Cancer Statistics, 2017. CA Cancer J Clin. Jan 2017; 67(1): 7-30. PMID 28055103
3. Gao L, Yang L, Qian S, et al. Cryosurgery would be An Effective Option for Clinically Localized Prostate Cancer: A Meta-analysis and Systematic Review. Sci Rep. Jun 07 2016; 6: 27490. PMID 27271239
4. Chin JL, Ng CK, Touma NJ, et al. Randomized trial comparing cryoablation and external beam radiotherapy for T2C-T3B prostate cancer. Prostate Cancer Prostatic Dis. 2008; 11(1): 40-5. PMID 17579613
5. Chin JL, Al-Zahrani AA, Autran-Gomez AM, et al. Extended followup oncologic outcome of randomized trial between cryoablation and external beam therapy for locally advanced prostate cancer (T2c-T3b). J Urol. Oct 2012; 188(4): 1170-5. PMID 22901586
6. Donnelly BJ, Saliken JC, Brasher PM, et al. A randomized trial of external beam radiotherapy versus cryoablation in patients with localized prostate cancer. Cancer. Jan 15 2010; 116(2): 323-30. PMID 19937954
7. Ball AJ, Gambill B, Fabrizio MD, et al. Prospective longitudinal comparative study of early health-related quality-of-life outcomes in patients undergoing surgical treatment for localized prostate cancer: a short-term evaluation of five approaches from a single institution. J Endourol. Oct 2006; 20(10): 723-31. PMID 17094746
8. Elkjaer MC, Borre M. Oncological outcome after primary prostate cryoablation compared with radical prostatectomy: a single-centre experience. Scand J Urol. Feb 2014; 48(1): 27-33. PMID 23597178
9. Gould RS. Total cryosurgery of the prostate versus standard cryosurgery versus radical prostatectomy: comparison of early results and the role of transurethral resection in cryosurgery. J Urol. Nov 1999; 162(5): 1653-7. PMID 10524891
10. Hubosky SG, Fabrizio MD, Schellhammer PF, et al. Single center experience with third-generation cryosurgery for management of organ-confined prostate cancer: critical evaluation of short-term outcomes, complications, and patient quality of life. J Endourol. Dec 2007; 21(12): 1521-31. PMID 18186694
11. Ramsay CR, Adewuyi TE, Gray J, et al. Ablative therapy for people with localised prostate cancer: a systematic review and economic evaluation. Health Technol Assess. Jul 2015; 19(49): 1-490. PMID 26140518
12. Xiong T, Turner RM, Wei Y, et al. Comparative efficacy and safety of treatments for localised prostate cancer: an application of network meta-analysis. BMJ Open. May 15 2014; 4(5): e004285. PMID 24833678

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13. Grimm P, Billiet I, Bostwick D, et al. Comparative analysis of prostate-specific antigen free survival outcomes for patients with low, intermediate and high risk prostate cancer treatment by radical therapy. Results from the Prostate Cancer Results Study Group. BJU Int. Feb 2012; 109 Suppl 1: 22-9. PMID 22239226
14. 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 (Report No. 12-05161-EF-1). Rockville, MD: Agency for Healthcare Research and Quality; 2011.
15. Robinson JW, Donnelly BJ, Siever JE, et al. A randomized trial of external beam radiotherapy versus cryoablation in patients with localized prostate cancer: quality of life outcomes. Cancer. Oct 15 2009; 115(20): 4695-704. PMID 19691092
16. Bahn DK, Lee F, Badalament R, et al. Targeted cryoablation of the prostate: 7-year outcomes in the primary treatment of prostate cancer. Urology. Aug 2002; 60(2 Suppl 1): 3-11. PMID 12206842
17. Donnelly BJ, Saliken JC, Ernst DS, et al. Prospective trial of cryosurgical ablation of the prostate: five-year results. Urology. Oct 2002; 60(4): 645-9. PMID 12385926
18. Ellis DS. Cryosurgery as primary treatment for localized prostate cancer: a community hospital experience. Urology. Aug 2002; 60(2 Suppl 1): 34-9. PMID 12206846
19. Long JP, Bahn D, Lee F, et al. Five-year retrospective, multi-institutional pooled analysis of cancer-related outcomes after cryosurgical ablation of the prostate. Urology. Mar 2001; 57(3): 518-23. PMID 11248631
20. Onik G. Image-guided prostate cryosurgery: state of the art. Cancer Control. Nov-Dec 2001; 8(6): 522-31. PMID 11807422
21. Robinson JW, Donnelly BJ, Saliken JC, et al. Quality of life and sexuality of men with prostate cancer 3 years after cryosurgery. Urology. Aug 2002; 60(2 Suppl 1): 12-8. PMID 12206843
22. Aus G, Pileblad E, Hugosson J. Cryosurgical ablation of the prostate: 5-year follow-up of a prospective study. Eur Urol. Aug 2002; 42(2): 133-8. PMID 12160583
23. De La Taille A, Benson MC, Bagiella E, et al. Cryoablation for clinically localized prostate cancer using an argon-based system: complication rates and biochemical recurrence. BJU Int. Feb 2000; 85(3): 281-6. PMID 10671882
24. Han KR, Cohen JK, Miller RJ, et al. Treatment of organ confined prostate cancer with third generation cryosurgery: preliminary multicenter experience. J Urol. Oct 2003; 170(4 Pt 1): 1126-30. PMID 14501706
25. Prepelica KL, Okeke Z, Murphy A, et al. Cryosurgical ablation of the prostate: high risk patient outcomes. Cancer. Apr 15 2005; 103(8): 1625-30. PMID 15747374

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26. Aus G. Cryosurgery for prostate cancer. J Urol. Nov 2008; 180(5): 1882-3. PMID 18801502
27. Lian H, Guo H, Gan W, et al. Cryosurgery as primary treatment for localized prostate cancer. Int Urol Nephrol. Dec 2011; 43(4): 1089-94. PMID 21475948
28. Williams SB, Lei Y, Nguyen PL, et al. Comparative effectiveness of cryotherapy vs brachytherapy for localised prostate cancer. BJU Int. Jul 2012; 110(2 Pt 2): E92-8. PMID 22192688
29. Jones JS, Rewcastle JC, Donnelly BJ, et al. Whole gland primary prostate cryoablation: initial results from the cryo on-line data registry. J Urol. Aug 2008; 180(2): 554-8. PMID 18550117
30. Tay KJ, Polascik TJ, Elshafei A, et al. Primary Cryotherapy for High-Grade Clinically Localized Prostate Cancer: Oncologic and Functional Outcomes from the COLD Registry. J Endourol. Jan 2016; 30(1): 43-8. PMID 26414656
31. Chin JL, Pautler SE, Mouraviev V, et al. Results of salvage cryoablation of the prostate after radiation: identifying predictors of treatment failure and complications. J Urol. Jun 2001; 165(6 Pt 1): 1937-41; discussion 1941-2. PMID 11371885
32. Robinson JW, Donnelly BJ, Coupland K, et al. Quality of life 2 years after salvage cryosurgery for the treatment of local recurrence of prostate cancer after radiotherapy. Urol Oncol. Nov-Dec 2006; 24(6): 472-86. PMID 17138127
33. Mouraviev V, Spiess PE, Jones JS. Salvage cryoablation for locally recurrent prostate cancer following primary radiotherapy. Eur Urol. Jun 2012; 61(6): 1204-11. PMID 22421081
34. Punnen S, Cooperberg MR, D'Amico AV, et al. Management of biochemical recurrence after primary treatment of prostate cancer: a systematic review of the literature. Eur Urol. Dec 2013; 64(6): 905-15. PMID 23721958
35. Peters M, Moman MR, van der Poel HG, et al. Patterns of outcome and toxicity after salvage prostatectomy, salvage cryosurgery and salvage brachytherapy for prostate cancer recurrences after radiation therapy: a multi-center experience and literature review. World J Urol. Apr 2013; 31(2): 403-9. PMID 22903773
36. Siddiqui KM, Billia M, Al-Zahrani A, et al. Long-Term Oncologic Outcomes of Salvage Cryoablation for Radio-Recurrent Prostate Cancer. J Urol. Oct 2016; 196(4): 1105-11. PMID 27157372
37. Wenske S, Quarrier S, Katz AE. Salvage cryosurgery of the prostate for failure after primary radiotherapy or cryosurgery: long-term clinical, functional, and oncologic outcomes in a large cohort at a tertiary referral centre. Eur Urol. Jul 2013; 64(1): 1-7. PMID 22840351

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38. Williams AK, Martinez CH, Lu C, et al. Disease-free survival following salvage cryotherapy for biopsy-proven radio-recurrent prostate cancer. Eur Urol. Sep 2011; 60(3): 405-10. PMID 21185115
39. Ng CK, Moussa M, Downey DB, et al. Salvage cryoablation of the prostate: followup and analysis of predictive factors for outcome. J Urol. Oct 2007; 178(4 Pt 1): 1253-7; discussion 1257. PMID 17698104
40. Ismail M, Ahmed S, Kastner C, et al. Salvage cryotherapy for recurrent prostate cancer after radiation failure: a prospective case series of the first 100 patients. BJU Int. Oct 2007; 100(4): 760-4. PMID 17662081
41. Friedlander DF, Gu X, Prasad SM, et al. Population-based comparative effectiveness of salvage radical prostatectomy vs cryotherapy. Urology. Mar 2014; 83(3): 653-7. PMID 24581527
42. Spiess PE, Levy DA, Pisters LL, et al. Outcomes of salvage prostate cryotherapy stratified by pre-treatment PSA: update from the COLD registry. World J Urol. Dec 2013; 31(6): 1321-5. PMID 23179729
43. National Comprehensive Cancer Network. Prostate Cancer. Version 2.2020. https://www.nccn.org/store/login/login.aspx?ReturnURL=https://www.nccn.org/professionals/physician_gls/pdf/prostate.pdf
44. American Urological Association (AUA). Clinically Localized Prostate Cancer: AUA/ASTRO/SUO Guideline. 2017; https://www.auanet.org/guidelines/prostate-cancer-clinically-localized-guideline.
45. Fenton JJ, Weyrich, MS, Durbin S, et al. U.S. Preventive Services Tast Force. Evidence Summary for prostate cancer screening. https://www.uspreventiveservicestaskforce.org/Page/Document/evidence-summary/prostate-cancer-screening1.
46. Centers for Medicare & Medicaid Services. National Coverage Determination (NCD) for Cryosurgery of Prostate (230.9). 2001; https://www.cms.gov/medicare-coverage-database/details/ncd-details.aspx?NCDId=123&ncdver=1&bc=AAAAQAAAAAAA&.

Policy History

Original Effective Date: 06/24/2002
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06/20/2002 Medical Policy Committee review

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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

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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.
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.

Next Scheduled Review Date: 04/2022

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	C61, C79.82, D07.5, Z85.46

*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

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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.

‡ 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.

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Whole Gland Cryoablation of Prostate Cancer

Policy # 00022
Original Effective Date: 06/24/2002
Current Effective Date: 05/10/2021

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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