



MASSACHUSETTS

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Medical Policy

Whole Gland Cryoablation of the Prostate

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Policy Number: 149

BCBSA Reference Number: 7.01.79

NCD/LCD: National Coverage Determination (NCD) for Cryosurgery of Prostate (230.9)

Related Policies

- Charged-Particle (Proton or Helium Ion) Radiotherapy for Neoplastic Conditions, [#437](#)
- Focal Treatments for Prostate Cancer, [#733](#)
- Stereotactic Radiosurgery and Stereotactic Body Radiation Therapy, [#277](#)
- Brachytherapy for Clinically Localized Prostate Cancer Using Permanently Implanted Seeds, [#175](#)
- High Dose Rate Temporary Prostate Brachytherapy, [#353](#)
- Intensity-Modulated Radiation Therapy (IMRT) of the Prostate, [#090](#)

Policy

Commercial Members: Managed Care (HMO and POS), PPO, and Indemnity

Whole gland cryosurgical ablation 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.

Medicare Members: Managed Care HMO BlueSM and Medicare PPO BlueSM

BCBSMA covers cryosurgical ablation of the prostate for the following indications for Medicare HMO Blue and Medicare PPO Blue members in accordance with CMS NCD:

- For primary treatment of patients with clinically localized prostate cancer, Stages T1-T3.
- As salvage therapy for patients with localized disease who have failed a trial of radiation therapy as primary treatment and meet one of the following requirements:
 - Stage T2 B or below,
 - Gleason score less than 9, or
 - PSA less than 8 ng/mL.

Cryosurgery as salvage is only covered for Medicare HMO Blue and Medicare PPO Blue members after the failure of a trial of radiation therapy, under the conditions noted above.

BCBSMA does not cover cryosurgery as salvage therapy for Medicare HMO Blue and Medicare PPO Blue members after failure of other therapies as the primary treatment in accordance with CMS NCD.

Medical necessity criteria and coding guidance can be found through the link below.

[National Coverage Determinations \(NCDs\)](#)

National Coverage Determination (NCD) for Cryosurgery of Prostate (230.9)

Note: To review the specific NCD, please remember to click “accept” on the CMS licensing agreement at the bottom of the CMS webpage.

Prior Authorization Information

Inpatient

- For services described in this policy, precertification/preauthorization **IS REQUIRED** for all products if the procedure is performed **inpatient**.

Outpatient

- For services described in this policy, see below for products where prior authorization **might be required** if the procedure is performed **outpatient**.

	Outpatient
Commercial Managed Care (HMO and POS)	Prior authorization is not required .
Commercial PPO and Indemnity	Prior authorization is not required .
Medicare HMO Blue SM	Prior authorization is not required .
Medicare PPO Blue SM	Prior authorization is not required .

CPT Codes / HCPCS Codes / ICD Codes

Inclusion or exclusion of a code does not constitute or imply member coverage or provider reimbursement. Please refer to the member’s contract benefits in effect at the time of service to determine coverage or non-coverage as it applies to an individual member. *A draft of future ICD-10 Coding related to this document, as it might look today, is included below for your reference.*

Providers should report all services using the most up-to-date industry-standard procedure, revenue, and diagnosis codes, including modifiers where applicable.

The following codes are included below for informational purposes only; this is not an all-inclusive list.

The above **medical necessity criteria MUST** be met for the following codes to be covered for Commercial Members: Managed Care (HMO and POS), PPO, and Indemnity:

CPT Codes

CPT codes:	Code Description
55873	Cryosurgical ablation of the prostate (includes ultrasonic guidance and monitoring)

The following ICD Diagnosis Codes are considered medically necessary when submitted with the CPT codes above if **medical necessity criteria** are met:

ICD-10 Diagnosis Codes

ICD-10-CM Diagnosis codes:	Code Description
C61	Malignant neoplasm of prostate

D07.5	Carcinoma in situ of prostate
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Description

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 2017.¹ 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.

Summary

Description

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 medical policy #[733](#).

Summary of Evidence

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.

Policy History

Date	Action
10/2020	BCBSA National medical policy review. Description, summary, and references updated. Policy statements unchanged.
10/2019	BCBSA National medical policy review. Description, summary and references updated. Policy statements unchanged.
2/2018	Clarified coding information.
9/2017	New references added from BCBSA National medical policy.
11/2016	New references added from BCBSA National medical policy.
10/2015	BCBSA National medical policy review.

	Information on focal therapy was removed from policy and the policy statement on focal therapy was deleted; "whole gland" was added to medically necessary policy statement and to the title of the policy. Effective 10/1/2015.
6/2014	Updated Coding section with ICD10 procedure and diagnosis codes, effective 10/2015.
6/2013	New references from BCBSA National medical policy.
11/2011-4/2012	Medical policy ICD 10 remediation: Formatting, editing and coding updates. No changes to policy statements.
9/2011	Reviewed - Medical Policy Group – Urology, Obstetrics and Gynecology. No changes to policy statements.
7/2011	Reviewed - Medical Policy Group – Hematology and Oncology. No changes to policy statements.
9/2010	Reviewed - Medical Policy Group - Hematology and Oncology. No changes to policy statements.
6/2010	Reviewed - Medical Policy Group - Urology. No changes to policy statements.
12/1/2009	National Policy review. Revision to policy statement.
6/2009	Reviewed - Medical Policy Group - Urology. No changes to policy statements.
6/2008	Reviewed - Medical Policy Group - Urology. No changes to policy statements.
6/2007	Reviewed - Medical Policy Group - Urology. No changes to policy statements.
6/2007	National Policy review. Revision to policy statement.

Information Pertaining to All Blue Cross Blue Shield Medical Policies

Click on any of the following terms to access the relevant information:

[Medical Policy Terms of Use](#)

[Managed Care Guidelines](#)

[Indemnity/PPO Guidelines](#)

[Clinical Exception Process](#)

[Medical Technology Assessment Guidelines](#)

References

1. Siegel RL, Miller KD, Jemal A. Cancer Statistics, 2017. CA Cancer J Clin. Jan 2017; 67(1): 7-30. PMID 28055103
2. 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
3. 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
4. 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
5. 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
6. 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

7. 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
8. 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
9. 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
10. 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
11. 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
12. 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
13. 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.
14. 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
15. 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
16. 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
17. 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
18. 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
19. Onik G. Image-guided prostate cryosurgery: state of the art. *Cancer Control*. Nov-Dec 2001; 8(6): 522-31. PMID 11807422
20. 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
21. 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
22. 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
23. 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
24. 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
25. Aus G. Cryosurgery for prostate cancer. *J Urol*. Nov 2008; 180(5): 1882-3. PMID 18801502
26. 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
27. 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
28. 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

29. 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
30. 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
31. 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
32. 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
33. 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
34. 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
35. 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
36. 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
37. 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
38. 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
39. 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
40. 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
41. 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
42. 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 Accessed June 16, 2020.
43. American Urological Association (AUA). Clinically Localized Prostate Cancer: AUA/ASTRO/SUO Guideline. 2017; <https://www.auanet.org/guidelines/prostate-cancer-clinically-localized-guideline>. Accessed June 16, 2020.
44. Fenton JJ, Weyrich, MS, Durbin S, et al. U.S. Preventive Services Task Force. Evidence Summary for prostate cancer screening. <https://www.uspreventiveservicestaskforce.org/Page/Document/evidence-summary/prostate-cancer-screening1>. Accessed June 16, 2020.
45. 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&>. Accessed June 16, 2020.