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Subject: Whole Gland Cryoablation of Prostate

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Position Statement	Billing/Coding	Reimbursement	Program Exceptions	Definitions	Related Guidelines
Other	References	Updates			

DESCRIPTION:

Whole gland cryoablation of the prostate (also known as total cryoablation, cryotherapy, or cryosurgery) is one of several methods to treat clinically localized prostate cancer. Whole gland cryoablaltion of the prostate may be considered an alternative to radical prostatectomy or external-beam radiotherapy (EBRT). Also, whole gland cryoablaltion of the prostate 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. EBRT requires multiple treatments, whereas only 1 treatment is usually required for total cryoablation.

There are several medical devices in use for ablation of prosthetic tissue that have received U.S. Food and Drug Administration (FDA) 510(k) clearance to market (e.g., AccuProbe® System modes 450, 550/530, and 600 series manufactured by Cryomedical Sciences Inc. and the Endocare Cryocare® CS manufactured by Endocare Inc.)

Summary and Analysis of Evidence: In a retrospective review (Tan et al 2022) retrospectively reviewed their prospectively collected cryosurgery database between January 2002 and September 2019 for men who were treated with WGC of the prostate at a tertiary referral center. Primary outcome includes biochemical recurrence-free survival (BRFS). Secondary outcomes included failure-free survival (FFS), metastasis-free survival (MFS) and adverse events. A total of 260 men were included in the study. Men having had prior treatment for prostate cancer (Pca) were excluded. Median follow-up was 107 months (interquartile range [IQR], 68.3-132.5 months). BRFS, FFS, and MFS at 10 years were 84%, 66%, and 96%, respectively. High risk D'Amico classification was associated with a lower BRFS and FFS on multivariable analysis. No patient had any Pca-related death during follow-up. American Urological Association symptoms score and bother index were unchanged following cryoablation. Median International Index of Erectile Function score precryoablation and post-cryoablation was 7 (IQR, 3-11) and 1 (IQR, 1-5),

respectively. Stress urinary incontinence, defined as requiring any protective pads only occurred in five patients (2%). No patient developed a fistula. Grade > 2 Clavien-Dindo adverse events occurred in six (2.3%) patients. The authors concluded that whole gland cryoablation (WGC) of the prostate can achieve excellent oncological and functional outcomes in men with localized Pca at the 10-year mark. Primary WGC may be a good option for men who desire to preserve urinary continence and have an excellent oncologic outcome.

Tan et al (2023) investigated oncological and functional outcomes for men treated with salvage whole-gland cryoablation (SWGC) of the prostate for radiation-resistant/recurrent prostate cancer (RRPC). The authors retrospectively reviewed their prospectively collected cryosurgery database between January 2002 and September 2019 for men who were treated with SWGC of the prostate at a tertiary referral center. The primary outcome was biochemical recurrence-free survival (BRFS) according to the Phoenix criterion. Secondary outcomes included metastasis-free survival, cancer-specific survival, and adverse events. A total of 110 men with biopsy-proven RRPC were included in the study. Median follow-up for patients without biochemical recurrence (BCR) after SWGC was 71 mo. (interquartile range [IQR] 42.3-116). BRFS was 81% at 2 yr and 71% at 5 yr. A higher prostate-specific antigen (PSA) nadir after SWGC was associated with worse BRFS. The median International Index of Erectile Function-5 score was 5 (IQR 1-15.5) before SWGC and 1 (IQR 1-4) after SWGC. Stress urinary incontinence, strictly defined as the use of any pads after treatment, was 5% at 3 mo. and 9% at 12 mo. Clavien-Dindo grade ≥3 adverse events occurred in three patients (2.7%). The authors concluded that in patients with localized RPPC, SWGC achieved excellent oncological outcomes with a low rate of urinary incontinence and represents an alternative to salvage radical prostatectomy. Patients with fewer positive cores and lower PSA tended to have better oncological outcomes following SWGC.

The NCCN (2025) panel recommends cryosurgery as a local therapy option for radiotherapy recurrence in the absence of metastatic disease.

POSITION STATEMENT:

Whole gland cryoablation of the prostate **meets the definition of medical necessity** as treatment of clinically localized (organ-confined (T1, T2)) prostate cancer for the following when performed with an FDA device approved for ablation of prostate tissue:

- As initial treatment; **OR**
- As salvage treatment of disease that recurs following radiotherapy.

BILLING/CODING INFORMATION:

CPT Coding:

55873	Cryosurgical ablation of the prostate (include ultrasonic guidance and monitoring)

ICD-10 Diagnosis Codes That Support Medical Necessity:

C61	Malignant neoplasm of prostate
C79.82	Secondary malignant neoplasm of genital organs
D07.5	Carcinoma in situ of prostate

Z85.46	Personal history of malignant neoplasm of prostate

REIMBURSEMENT INFORMATION:

None applicable.

PROGRAM EXCEPTIONS:

Federal Employee Program (FEP): Follow FEP guidelines.

State Account Organization (SAO): Follow SAO guidelines.

Medicare Advantage products:

No Local Coverage Determination (LCD) was found at the time of the last guideline reviewed date.

The following National Coverage Determinations (NCDs) was reviewed on the last guideline reviewed date: Cryosurgery of Prostate, (230.9) located at cms.gov.

If this Medical Coverage Guideline contains a step therapy requirement, in compliance with Florida law 627.42393, members or providers may request a step therapy protocol exemption to this requirement if based on medical necessity. The process for requesting a protocol exemption can be found at Coverage Protocol Exemption Request.

DEFINITIONS:

Gleason Grading System (Score): a method of classifying the grade of cancer. The pathologist assigns a primary grade from 1 to 5 to the pattern occupying the greatest area of the specimen. A secondary grade is assigned to the pattern occupying the second largest area. These two grades are added to determine the Gleason score, which ranges from 2 to 10. Tumors with a Gleason score of 2 to 4 have lower biological aggressiveness, those with a score of 5 to 6 have an intermediate aggressiveness, and those with a score of 7 or higher are biologically aggressive tumors (American Urological Association, 2009).

Prostate: a gland in the male, which surrounds the neck of the bladder and the urethra. The prostate consists of a median lobe and two lateral lobes, and is made up partly of glandular matter.

Stages T1 or T2: organ-confined cancer.

Stages T3: locally advanced cancer.

Stage T2B (B2): cancer detected during digital rectal examination as a hard lump on the prostate and involves both sides of the prostate gland or is larger than 2 centimeters.

RELATED GUIDELINES:

Cryosurgical Ablation of Solid Tumors Other Than Liver or Prostate Tumors, 02-99221-12

OTHER:

Other names used to report cryosurgical ablation of the prostate:

Note: The use of specific product names is illustrative only. It is not intended to be a recommendation of one product over another, and is not intended to represent a complete listing of all products available.

Ablation, Prostate
Cryosurgery, Prostate
Cryotherapy, Prostate
Salvage Cryotherapy
Transperineal Percutaneous Prostate Cryosurgery

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COMMITTEE APPROVAL:

This Medical Coverage Guideline (MCG) was approved by the Florida Blue Medical Policy and Coverage Committee on 09/25/25.

GUIDELINE UPDATE INFORMATION:

05/25/00	Medical Coverage Guideline Developed.
06/15/02	Annual review. Revised description section. Added coverage criteria.
06/15/04	Scheduled review, no revisions. No longer scheduled for review.
08/15/07	Reformatted guideline. Revise coverage statement. Updated description section. Revised ICD-9 diagnoses code (185) descriptor, and updated references.
09/15/08	Scheduled review. No change in position statement, and updated references.
10/15/09	Annual review. No change in position statement, and updated references.
01/01/10	Annual HCPCS coding update. Revised descriptor for code 55873.
01/01/11	Revision; added related ICD-10 codes.
05/11/14	Revision: Program Exceptions section updated.
11/01/15	Revision: ICD-9 Codes deleted.
03/15/17	Revision; Changed guideline name to Whole Gland Cryoablation of Prostate Cancer, revised description and position statement. Updated ICD-10 diagnoses codes (added C79.2, D07.5 and Z85.46). Updated other section and references.
09/15/19	Review; no change in position statement. Updated references.
10/15/21	Review; no change in position statement. Updated references.
10/15/23	Review; no change in position statement. Updated references.
10/15/25	Review; no change in position statement. Updated references.