

## Medical Coverage Policy | Whole Gland Cryoablation of Prostate Cancer



**EFFECTIVE DATE:** 02|17|15

**POLICY LAST UPDATED:** 09|04|2024

### OVERVIEW

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.

This policy is applicable to Commercial Products only. For Medicare Advantage Plans, see Related Policies section.

### PRIOR AUTHORIZATION

Not applicable

### POLICY STATEMENT

#### Commercial Products

Whole gland cryoablation of the prostate 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.

### MEDICAL CRITERIA

Not applicable

### BACKGROUND

Prostate cancer is the most commonly diagnosed cancer and the second leading cause of cancer deaths among men in the United States, 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.

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, and treatment-related morbidity. High-quality data comparing cryoablation with external beam radiation therapy (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.

#### Regulatory Status

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

#### COVERAGE

Benefits may vary between groups and contracts. Please refer to the appropriate Evidence of Coverage, Subscriber Agreement for applicable Not Medically Necessary benefits/coverage.

#### CODING

##### Commercial Products

The following code(s) is medically necessary when filed with a covered \*ICD-10 Diagnosis Code(s) below;

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

##### \*ICD-10 Covered Diagnosis Code(s)

C61

C79.82

D07.5

Z85.46

#### RELATED POLICIES

Focal Treatments for Prostate Cancer

Medicare Advantage Plans National and Local Coverage Determinations

#### PUBLISHED

Provider Update, November 2024

Provider Update, November 2023

Provider Update, January 2023

Provider Update, October 2021

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