Medical Coverage Policy | Whole Gland Cryoablation of Prostate Cancer (Formally Cryoablation of Prostate)

EFFECTIVE DATE:02|17|15
POLICY LAST UPDATED: 11|07|2017

OVERVIEW

Cryoablation, also known as cryotherapy or cryosurgery, of prostate cancer is a technique in which cryoprobes are inserted percutaneously into the prostate gland to rapidly freeze and thaw tissue-causing necrosis. While most studies use total cryoablation, subtotal cryoablation is an emerging technique.

PRIOR AUTHORIZATION

Not applicable

POLICY STATEMENT

This policy is applicable to Commercial Products only. For Blue CHiP for Medicare, see related policy section.
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 radiation therapy.

Subtotal prostate cryoablation is considered not medically necessary in the treatment of prostate cancer as there is a lack of peer reviewed scientific evidence to support if efficacy.

MEDICAL CRITERIA

Not applicable

BACKGROUND

Cryoablation, also known as cryotherapy or cryosurgery, of prostate cancer is a technique in which cryoprobes are inserted percutaneously into the prostate gland to rapidly freeze and thaw tissue causing necrosis. Cryoablation is one of several methods available to treat clinically localized prostate cancer and may be considered an alternative to radical prostatectomy or radiotherapy. It also 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 such that tissue necrosis follows.

Cryosurgical ablation is less invasive than radical prostatectomy and recovery time may be shorter. While external beam radiotherapy (EBRT) requires multiple treatments, typically only 1 treatment is required for cryoablation. Subtotal prostate cryoablation is also being evaluated as a form of more localized therapy (referred to by some as focal or organ-preserving therapy or male lumpectomy) for small localized prostate cancers.

The available evidence for use of cryotherapy in the treatment of clinically localized (organ-confined) prostate cancer when performed as initial treatment or as salvage treatment of disease that recurs following radiation therapy is sufficient to demonstrate improvement in net health outcome. This conclusion is based on the extensive data from cohort studies and clinical input including an indirect chain of evidence and the recognition that the data for this long-used technique are similar to data for a number of accepted techniques. While the data for treatment of recurrence after radiotherapy are limited, these patients have few options; one option with recurrence is prostatectomy, which can be difficult in tissue that has been irradiated. However, for patients with recurrence after radiotherapy who elect further treatment, based on the limited data available, cryosurgical treatment does appear to produce anti-tumor activity.

Given the lack of long-term follow-up data, including a lack of comparative studies, subtotal prostate cryoablation is considered investigational.

Regulatory Status
Cryoablation of prostate cancer uses available cryoablation systems and, as a surgical procedure, is not subject to regulation by the U.S. Food and Drug Administration (FDA). A number of cryoablation systems and cryoprobes have general surgical FDA 510(k) marketing clearance. Examples of cryoablation devices that specifically mention treatment of prostate cancer in their marketing clearance are 2 Endocare® Inc. devices, Cryocare CS® and Cryocare CN2® systems, and 2
Galil Medical devices, Visual-ICE® Cryoablation System and IceRod® CX Cryoablation Needle.

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
The following code is medically necessary when filed with a covered diagnosis below
55873 Cryoablate Prostate

ICD10
C61, C79.82, D07.5, Z85.46

RELATED POLICIES
BlueCHiP for Medicare National and Local Coverage Determinations Policy

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