# Protocol

# Cryoablation of Prostate Cancer

(70179)

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| **Medical Benefit** | | **Effective Date**: 10/01/14 | **Next Review Date**: 07/15 |
| **Preauthorization** | No | **Review Dates**: 02/07, 02/08, 05/09, 01/10, 01/11, 01/12, 09/12, 07/13, 07/14 | |

*The following Protocol contains medical necessity criteria that apply for this service. It is applicable to Medicare Advantage products unless separate Medicare Advantage criteria are indicated. If the criteria are not met, reimbursement will be denied and the patient cannot be billed.* ***Preauthorization is not required.*** *Please note that payment for covered services is subject to eligibility and the limitations noted in the patient's contract at the time the services are rendered.*

## Description

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.

*Background*

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 one 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.

*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 two Endocare® Inc. devices, Cryocare CS® and Cryocare CN2® systems, and two Galil Medical devices, Visual-ICE® Cryoablation System and IceRod® CX Cryoablation Needle.

*Related Protocols*

Stereotactic Radiosurgery and Stereotactic Body Radiation Therapy

Charged-Particle (Proton or Helium Ion) Radiation Therapy

## Policy (Formerly Corporate Medical Guideline)

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 treatment.

Subtotal prostate cryoablation is considered **investigational** in the treatment of prostate cancer.

**Medicare Advantage**

For Medicare Advantage, cryosurgery of the prostate gland is considered **medically necessary** as primary treatment for patients with clinically localized prostate cancer, Stages T1-T3.

Salvage cryosurgery of the prostate after *radiation failure,* for recurrent cancer, is **medically necessary** for those patients with localized disease who:

1. Have failed a trial of radiation therapy as their primary treatment; and
2. Meet one of the following conditions: Stage T2B or below, Gleason score < 9, PSA < 8 ng/mL.

Cryosurgery as salvage therapy is **investigational** after failure of other therapies as the primary treatment. Cryosurgery as salvage is only **medically necessary** after the failure of a trial of radiation therapy, under the conditions noted above.

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Services that are the subject of a clinical trial do not meet our Technology Assessment Protocol criteria and are considered investigational. *For explanation of experimental and investigational, please refer to the Technology Assessment Protocol.*

It is expected that only appropriate and medically necessary services will be rendered. We reserve the right to conduct prepayment and postpayment reviews to assess the medical appropriateness of the above-referenced procedures. **Some of this Protocol may not pertain to the patients you provide care to, as it may relate to products that are not available in your geographic area.**

**References**

We are not responsible for the continuing viability of web site addresses that may be listed in any references below.

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