**Whole Gland Cryoablation of Prostate Cancer**

**Medical Benefit**

**Effective Date:** 10/01/15  
**Next Review Date:** 07/17

**Preauthorization**

**Review Dates:** 02/07, 02/08, 05/09, 01/10, 01/11, 01/12, 09/12, 07/13, 07/14, 07/15, 07/16

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**Preauthorization is not required.**

*The following Protocol contains medical necessity criteria that apply for this service. The criteria are also applicable to services provided in the local Medicare Advantage operating area for those members, unless separate Medicare Advantage criteria are indicated. If the criteria are not met, reimbursement will be denied and the patient cannot be billed. 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.*

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**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. This Protocol reviews evidence on the use of total (whole gland, definitive therapy) cryoablation compared with external beam radiotherapy (EBRT), radical prostatectomy or other alternative definitive treatments for patients with organ-confined (localized) prostate cancer.

**Summary of Evidence**

The available evidence for use of whole gland 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 radiotherapy 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, such as radical prostatectomy and external beam radiotherapy (EBRT).

While the evidence for outcomes of treatment for recurrence after EBRT is limited, such 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 evidence available, cryosurgical treatment does appear to produce antitumor activity.

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**Policy**

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.
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 less than 9, PSA less than 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.

Background

Whole gland (also known as total) cryoablation is one of several methods available to treat clinically localized prostate cancer and may be considered an alternative to radical prostatectomy or EBRT. 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. EBRT requires multiple treatments, whereas only one treatment is usually required for total cryoablation.

Regulatory Status

Cryoablation of prostate cancer is a surgical procedure that uses previously approved and available cryoablation systems. As a surgical procedure cryoablation of the prostate is not subject to FDA approval.

Related Protocols

Charged-Particle (Proton or Helium Ion) Radiotherapy
Stereotactic Radiosurgery and Stereotactic Body Radiotherapy

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.


33. National Coverage Determination (NCD) for Cryosurgery of Prostate (230.9), Effective Date of this Version 7/1/2001.