### Whole Gland Cryoablation of Prostate Cancer

**Medical Benefit**
- **Effective Date:** 10/01/15
- **Next Review Date:** 07/19
- **Preauthorization:** No
- **Review Dates:** 02/07, 02/08, 05/09, 01/10, 01/11, 01/12, 09/12, 07/13, 07/14, 07/15, 07/16, 07/17, 07/18

**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.

<table>
<thead>
<tr>
<th>Populations</th>
<th>Interventions</th>
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| Individuals:  
  - Who are considering initial treatment for localized prostate cancer | Interventions of interest are:  
  - Whole gland cryoablation | Comparators of interest are:  
  - Radiotherapy  
  - Radical prostatectomy  
  - Active surveillance | Relevant outcomes include:  
  - Overall survival  
  - Disease-specific survival  
  - Symptoms  
  - Functional outcomes  
  - Quality of life  
  - Treatment-related morbidity |
| Individuals:  
  - Who need salvage treatment for recurrence of localized prostate cancer following radiotherapy | Interventions of interest are:  
  - Whole gland cryoablation | Comparators of interest are:  
  - Radical prostatectomy  
  - Brachytherapy | Relevant outcomes include:  
  - Overall survival  
  - Disease-specific survival  
  - Symptoms  
  - Functional outcomes  
  - Quality of life  
  - Treatment-related morbidity |

### DESCRIPTION

Cryoablation, also known as cryotherapy or cryosurgery, is a cancer-fighting technique that attacks cancer cells with extremely cold gas. This technique can be used to combat prostate cancer by percutaneously inserting thin, needle-like cryoprobes into the prostate gland; then, sending very cold gas down the cryoprobes to rapidly freeze and thaw the tissue, causing necrosis. This protocol evaluates evidence on the use of total (whole gland, definitive therapy) cryoablation.

### SUMMARY OF EVIDENCE

For individuals who are considering initial treatment for localized prostate cancer who receive whole gland cryoablation, the evidence includes several systematic reviews, two randomized controlled trials, and many comparative and noncomparative observational studies. Relevant outcomes are overall survival, disease specific survival, symptoms, functional outcomes, quality of life, and treatment-related morbidity. High quality data comparing cryoablation with external-beam radiotherapy, radical prostatectomy, or active surveillance are
lacking, but available data suggest similar overall survival and disease-specific survival rates compared with radical prostatectomy and external-beam radiotherapy. The evidence is sufficient to determine that the technology results in a meaningful improvement in the net health outcome.

For individuals who have salvage treatment for recurrence of localized prostate cancer following radiotherapy who receive whole gland cryoablation, the evidence includes primarily noncomparative case series and a few retrospective studies comparing salvage cryoablation with salvage prostatectomy. Relevant outcomes are overall survival, disease-specific survival, symptoms, functional outcomes, quality of life, and treatment-related morbidity. High-quality data comparing cryoablation to prostatectomy is mixed, and evidence comparing cryoablation to brachytherapy is lacking. Men in this group have few options and prostatectomy can be difficult in tissue that has been irradiated. The evidence is sufficient to determine that the technology results in a meaningful improvement in the net health outcome.

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, also known as cryosurgical ablation, 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 used to treat clinically localized prostate cancer and may be considered an alternative to radical prostatectomy or external-beam radiotherapy. 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 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; and as a surgical procedure, it is not subject to regulation by the U.S. Food and Drug Administration.

RELATED PROTOCOLS
Charged-Particle (Proton or Helium Ion) Radiotherapy for Neoplastic Conditions
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.


49. National Coverage Determination (NCD) for CRYOSURGERY of PROSTATE (230.9), Effective Date of this Version 7/1/2001.