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Medical policies in conjunction with other nationally recognized standards of care are used to make medical coverage decisions.

Title

Prostate Rectal Spacers Policy (SpaceOAR)

Indication/Usage:

SpaceOAR is a biodegradable polyethylene glycol hydrogel that is injected between the prostate and rectum under ultrasound guidance. Once injected as a gel, the liquid solidifies within seconds into a hydrogel to temporarily position the anterior rectal wall away from the prostate during radiotherapy for prostate cancer and in creating this space it is the intent to reduce the radiation dose delivered to the anterior rectum. The absorbable spacer maintains space for the entire course of prostate radiotherapy treatment and is completely absorbed by the patient's body over time.

Medical Indications for Authorization

Hydrogel spacer use during radiotherapy for prostate cancer is considered medically necessary when the following criteria are met:

- Prostate cancer that is considered low or favorable intermediate-risk
- Tumor is confined to prostate
- PSA less than 20
- Gleason score less than or equal to 7
- Prostate volume less than 80cm³
- No prior hormone therapy, surgery or radiation of the prostate
- No active bleeding disorder
- Patient will be treated with a radiation source to the prostate

CPT Code 55874

Limitations

SummaCare considers transperineal periprostatic placement of biodegradable material experimental and investigational for all other indications.

Coverage Decisions

CMS LCD ID L37485 Prostate Rectal Spacers

Coverage Guidance

Coverage Indications, Limitations, and/or Medical Necessity

Polyethylene-glycol (PEG) hydrogel is covered **ONCE** in patients with clinically localized prostate cancer with **BOTH** the following:

1. Inclusion criteria including **ALL** of the following:
 - a. Low* or Favorable Intermediate Prostate Cancer Risk Group (1-5) (AUA or NCCcriteria (6,7))
 - b. Dose escalated (≥ 76 Gy) conventional fractionation (1.8-2 Gy fractions) or moderate hypofractionation (HFX) (2.4-3.4 Gy fractions) IG-IMRT planned (7,8,9,25-27)
 - c. Eastern Cooperative Oncology Group (ECOG) performance status ≤ 1 (4)
 - d. Modern localization techniques insufficient to improve oncologic cure rates and/or reduce side effects due to **AT LEAST ONE** of the following (7):
 - i. Anatomic geometry precluding ideal rectal constraints
 - Conventional fractionation (V70 <10%, V65 <20%, V40 <40%) (10)
 - Moderate HPX (dose constraints not yet standardized; employ those used in the supporting phase III trials) (25)
 - ii. Medication usage (e.g., anticoagulants) (8,11,12)
 - iii. Comorbid conditions (e.g., increased age, Hx MI or CHF) (11)
2. No Exclusion criteria including **ALL** of the following:
 - a. Less than 5 year life-expectancy and asymptomatic (7)
 - b. Prior prostate cancer treatment (surgery or RT) (1,3,4,8)

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- c. Active bleeding disorder or clinically significant coagulopathy (8)

- d. Active inflammatory or infectious disease in the perineum or injection area (e.g., prostatitis, anorectal IBD) (1,3,8)
- e. Prostate volume > 80 cc (1,3,4)

*Life expectancy \geq 20 y (very low risk); \geq 10 y (low risk) (7)

Prostate rectal spacers are various materials or devices placed between the prostate and anterior wall of the rectum for use in men receiving radiation therapy for prostate cancer. The anterior wall of the rectum is considered a major dose-limiting factor in radiation therapy of prostate cancer. Physical separation is proposed to allow reduced toxicity and treatment intensification.

Plans Covered By This Policy

Commercial and Medicare

Self-funded Commercial groups refer to plan document for coverage

Sources Reviewed

Absorbable Perirectal Spacer (SpaceOAR System; Boston Scientific) During Radiation Therapy for Prostate Cancer. Hayes. from <https://evidence.hayesinc.com/>

Prostate Rectal Spacers CMS. from <https://www.cms.gov/>

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<https://www.cms.gov/medicare>

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