



Transperineal Placement of Biodegradable Material (SpaceOAR®) for Prostate Cancer

Last Revision/Review Date: July 17, 2019

P&P # C.5.35

Policy

The Medical Management Department reviews referral requests for authorization of Transperineal Placement of Biodegradable Material (SpaceOAR®) for patients with Prostate Cancer.

This Medical Policy does not constitute medical advice. When deciding coverage, the enrollee's specific plan document must be referenced. The terms of an enrollee's plan document (Certificate of Coverage (COC) or Summary Plan Description (SPD)) may differ from this Medical Policy. In the event of a conflict, the enrollee's specific benefit plan document supersedes this Medical Policy. All reviewers must first identify enrollee eligibility, any federal or state regulatory requirements, and the plan benefit coverage prior to use of this Medical Policy. Other Policies and Coverage Determination Guidelines may apply. Quartz reserves the right, in its sole discretion, to modify its Policies and Guidelines as necessary.

Procedure

SpaceOAR® System: is a transperineal hydrogel injection placed into the space between the prostate and rectum. The hydrogel is a biodegradable material (polyethylene glycol) that is used to temporarily position the anterior rectal wall away from the prostate during radiotherapy for prostate cancer. The space that's created by the hydrogel is intended to reduce the radiation dose exposure delivered to the anterior rectum, reducing rectal complications from radiation therapy intended for the prostate. The hydrogel liquefies via hydrolysis and is absorbed and cleared via renal filtration after 6 months of implantation. This procedure is done as an outpatient in the urologist office.

Procedure

A. Documentation Required:

In order to facilitate the authorization process, referral requests **MUST** include the following:

1. Diagnosis and staging of prostate cancer. Prostate cancer should not have evidence of T3 rectal invasion or posterior extension.
2. Treatment plan by a Radiation Oncologist includes radiotherapy to the prostate.
3. Documentation of adequate renal function or for patients with chronic renal disease (e.g., Serum Cr ≥ 2 or on dialysis) with approval of treating Nephrologist.
4. The provider performing the procedure is a Urologist certified in the SpaceOAR procedure or the Urologist is familiar with ultrasound guided transperineal procedures and is in the process of SpaceOAR certification.

B. Criteria for Medical Necessity

Transperineal periprostatic placement of biodegradable material (e.g., SpaceOAR®) is considered medically necessary when **ALL** the following criteria are met (a-e):

- a. The patient has a diagnosis of prostate cancer without evidence of local advancement (e.g. rectal invasion or posterior extension); **AND**

- b. Patient does not have an active bleeding disorder; **AND**
- c. The treatment plan by a Radiation Oncologist includes radiotherapy to the prostate; **AND**
- d. The procedure will be performed by a Urologist certified in the SpaceOAR® procedure or a Urologist who is familiar with ultrasound guided transperineal procedures and is in the process of SpaceOAR certification; **AND**
- e. Evidence of adequate renal function with serum Creatinine < 2.0mg/dl and not receiving dialysis, or the approval of the treating Nephrologist.

C. Conditions Considered Experimental/Investigational (not an all-inclusive list)

- 1. Transperineal periprostatic placement of biodegradable material experimental and investigational for all other indications.
- 2. Prostate cancer which is locally advanced (e.g., there is rectal invasion or T3 class tumor and posterior extension).
- 3. Use in patients with prostate cancer undergoing low dose rate (LDR) brachytherapy.
- 4. Use in patients with renal failure evidenced by a serum creatinine of ≥ 2.0 or on hemo or peritoneal dialysis unless approved by the treating nephrologist.

CPT/HCPCS Codes:

55874	Transperineal placement of biodegradable material, peri-prostatic, single or multiple injection(s), including image guidance, when performed.
-------	---

References

Hamstra D, Mariados N, Sylvester J, et. Al, Continued benefit to Rectal Separation for prostate Radiation Therapy: Final results of Phase III trial. *Int J Radiation Oncol Biol Phys.* 2017;97(5): 976-985.

Hamstra D, Mariados N, Sylvester J, et. Al, Sexual quality of life following prostate intensity modulated radiation therapy with a rectal/prostate spacer: secondary analysis of a phase 3 trial. *Pract Radiat Oncol.* 2018;8:e7-e15.

Hayes, Inc. Absorbable Perirectal Spacer (SpaceOar SYSTEM; AUGMENIX Inc.) During Radiation Therapy for Prostate Cancer. Publication date: April 10, 2018. Annual review: May 1, 2019. Accessed May 13, 2019.

Karsh LI, Gross ET, Pieczonka CM, et al. Absorbable hydrogel spacer use in prostate radiotherapy: A comprehensive review of phase 3 clinical trial published data. *Urology.* 2018;115:39-44.

Mariados N, Sylvester J, Shah D, et.,al; Hydrogel Spacer Prospective Multicenter Randomized Controlled Pivotal Trial: Dosimetric and Clinical Effects of Perirectal Spacer Application in Men Undergoing Prostate Image Guided Intensity Modulated Radiation Therapy. *Int J Radiation Oncol Biol Phys.* 2015;92(5):971-977.

NCCN Clinical Practice Guidelines in Oncology. Prostate Cancer. Version 2.2019, April 17, 2019. Accessed May 13, 2019.

Pinkawa M, et al. Quality of life after radiation therapy for prostate cancer with a hydrogel spacer: 5-year results. *Int J Radiation Oncol Biol Phys.* 2017;99(2):374-37