KAISER PERMANENTE® Mid-Atlantic States	**Trans-perineal Placement of Absorbable Peri-rectal Spacer for Prostate Cancer Radiotherapy Medical Coverage Policy**

Utilization *ALERT*

- Prior to use of this MCP for evaluation of medical necessity, benefit coverage MUST be verified in the member's EOC or benefit document.
- For Medicare members, please refer to CMS guidelines through Medicare Coverage Database requirements.
- Note: After searching the Medicare Coverage Database, if no NCD/LCD/LCA is found, then use the policy referenced above for coverage guidelines

I. Service: Trans-Perineal Placement of Absorbable Peri-Rectal Spacer (SpaceOAR) for Prostate Cancer Radiotherapy

II. Specialty: Radiation Oncology

III. Description of Procedure or Service:

Men who undergo radiotherapy for prostate cancer as a result can develop radiation toxicity, also known as radiation proctitis, a potential side effect that can be permanent after radiation.

To reduce late-onset radiation-induced toxicity from irradiation of the rectum during prostate radiotherapy, an absorbable gel material was developed to be injected between the rectum and prostate prior to radiotherapy delivery. This material temporarily provides additional space between the area of treatment (prostate) and the organ at risk (OAR, rectum during treatment.

The only FDA-approved biodegradable gel material (spacer) available for use in the United States that can be used in this fashion is SpaceOAR ®. The SpaceOAR™ System (Augmenix Inc. Bedford, MA, USA) is a biodegradable hydrogel spacer, cleared by the FDA on April 1, 2015, for marketing through the 513(a) (1) (de novo) process. The FDA approval classifies the SpaceOAR System, and equivalent devices of this generic type, into class II under the generic name, "*Absorbable perirectal spacer*" and product code OVB.

SpaceOAR ® is made of biodegradable polyethylene glycol (PEG) - based hydrogel, injected transperineally between the prostate capsule and the rectum under transrectal ultrasound guidance in preparation for radiation treatment of prostate cancer. Insertion of the implantable trans-perineal spacer can result in reduction of radiation-induced late-onset rectal toxicity.

Modern, highly conformal radiation techniques which can better shape and target the radiation than older approaches have reduced the toxicity of treatments in the past decade without the need for SpaceOAR.

SpaceOAR placement is not without risk, which can include pain, bleeding, infection, and organ perforation. Given the potential for toxicity from placement and the already favorable toxicity profile of treatment without SpaceOAR, it is preferred that SpaceOAR only be used when normal rectal constraints cannot be met without its use.

IV. Indications for Referral

Placement of SpaceOAR can be considered for men with malignant non-metastatic neoplasm of prostate undergoing radiation therapy. In addition, the following indications, consistent with the original evaluation, should be maintained when the patient is receiving radiation therapy.
Placement of Space Oar is covered when ALL of the following criteria are met:

A. Stage T1 or T2 prostate cancer;
B. Gleason score of <= 7;
C. Prostate-specific antigen (PSA) of <=20ng/ml;
D. Zubrod performance status 0 to 1;
E. No evidence of metastasis; and
F. Documentation in the medical record that the rectal dose volume histogram (DVH) constraints cannot be met without SpaceOAR use

V. Contraindications

SpaceOAR is contraindicated and not recommended for the following conditions:

A. Prostate volume of > 80 cm^3;
B. > 50% positive biopsy cores;
C. Metastatic disease;
D. Indicated or recent androgen deprivation therapy;
E. Prior prostate surgery;
F. Locally advanced prostate cancer;
G. Men who have preciously undergone high-intensity focused ultrasound, cryotherapy, or radiotherapy of the prostate;
H. Prostatitis or anorectal inflammatory diseases for which there is increased risk of ulceration, fistula, or bleeding, such as ulcerative colitis or Crohn's disease; and
I. Clinically significant coagulopathies or active bleeding disorders;
It may be possible to temporarily discontinue anticoagulants for the purpose of SpaceOAR placement for patients who are already on anticoagulants prior to radiotherapy of the prostate.

VI. Definitions

A. Zubrod or ECOG (Eastern Cooperative Oncology Group) scale—a scale for indicating a patient's functional level
   - 0, asymptomatic
   - 1, symptomatic but fully ambulatory, cares for self
   - 2, symptomatic, in bed < 50% of day, occasional assistance
   - 3, symptomatic, in bed > 50% of the day but not bedridden, nursing care needed
   - 4, bedridden

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Approval History

Effective June 01, 2016, state filing is no longer required per Maryland House Bill HB 798 – Health Insurance – Reporting

Date approved by RUMC*	Date of Implementation
09/26/2019	09/26/2019
09/24/2020	09/24/2020
09/27/2021	09/27/2021
09/23/2022	09/23/2022
08/24/2023	08/24/2023
08/28/2024	08/28/2024

*The Regional Utilization Management Committee received delegated authority in 2011 to review and approve designated Utilization Management and Medical Coverage Policies by the Regional Quality Improvement Committee.

Note: Kaiser Permanente Mid-Atlantic States (KPMAS) include referral and authorization criteria to support primary care and specialty care practitioners, as appropriate, in caring for members with selected conditions. Medical Coverage Policies are not intended or designed as a substitute for the reasonable exercise of independent clinical judgment by a practitioner in any set of circumstances for an individual member.