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Medical Policy

Subject:	Perirectal Spacers for Use During Prostate Radiotherapy		
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Description/Scope

This document addresses the use of perirectal spacers placed prior to prostate radiotherapy as a method of rectal displacement. Such products include SpaceOAR® (Boston Scientific, Marlborough, MA.), an injectable liquid hydrogel product intended to create distance and serve as a spacer between the prostate and the anterior rectal wall in individuals undergoing radiotherapy for prostate cancer.

Position Statement

~~Investigational and Not~~ Medically Necessary:

Use of perirectal spacers during prostate radiotherapy is considered ~~**investigational and not medically necessary** for all indications.~~ **medically necessary** for individuals planning to undergo hypofractionated radiation therapy or stereotactic body radiotherapy when none of the following conditions are present:

- Tumor invasion into rectum
- Posterior extraprostatic extension

Investigational and Not Medically Necessary

Use of perirectal spacers is considered **investigational and not medically necessary** when the criteria above are not met.

Rationale

A concern during prostate radiotherapy is rectal toxicity due to the exposure of healthy rectal tissue to therapeutic doses of radiation intended for the prostate. One proposed method of reducing rectal toxicity is to create a buffer

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area in the perirectal space between the prostate and the rectum. Such a buffer is intended to create distance between the prostate and rectum to move the rectum away from the treatment field.

~~*SpaceOAR*~~

~~At this time, o~~Only one product has been approved by the U.S. Food and Drug Administration (FDA) for such use. The SpaceOAR ~~(Boston Scientific, .)~~ system was cleared by the FDA on July 19, 2019. The SpaceOar is a synthetic, absorbable polyethylene glycol (PEG)-based hydrogel which, when injected, creates a space between the anterior rectal wall and the prostate in order to reduce the radiation dose delivered to the anterior rectum. ~~Questions remain about whether the use of SpaceOAR results in improved clinical outcomes.~~

External Radiotherapy

Song and colleagues (2013) reported the results of an industry sponsored prospective pilot clinical trial involving 54 subjects receiving intensity modulated radiation therapy (IMRT) for prostate cancer. All subjects underwent baseline scans and then were injected with SpaceOAR and rescanned. Intensity modulated radiation therapy plans were created on both scans for comparison. The authors reported that use of SpaceOAR resulted in ≥ 7.5 mm prostate-rectal separation in 95.8% of subjects and 95.7% had decreased rectal V70 of ≥ 25%, with a mean reduction of 8.0 Gy. No significant differences were reported in pre-injection and post-injection prostate planning target volume (PTV), or rectal and bladder volumes. Plan conformities were significantly different before versus after injection (p=0.02). Plans with worse conformity indexes after injection compared with before injection (n=13) still had improvements in rectal V70. The authors reported that in multiple regression analysis, greater post-injection reduction in V70 was associated with significantly decreased relative post-injection plan conformity ~~(p=0.01)~~. No significant relationships between reduction in V70 and the other characteristics analyzed were reported. The authors concluded that injection of SpaceOAR resulted in dose reductions to the rectum for > 90% of subjects treated. Furthermore, they stated that rectal sparing was statistically significant across a range of 10 to 75 Gy.

Gastrointestinal and genitourinary toxicity were recorded during treatment for up to 12 months in 52 subjects in whom the SpaceOAR system was injected prior to IMRT radiotherapy to a dose of 78 Gy (Uhl, 2014). Of the subjects treated, 39.6% and 12.5% experienced acute Grade 1 and Grade 2 gastrointestinal (GI) toxicity using the RTOG/EORTC (Radiation Therapy Oncology Group and the European Organization for Research and Treatment of Cancer) criteria, respectively. No Grade 3 or Grade 4 acute GI toxicity was reported. Only 4.3% of subjects showed late Grade 1 GI toxicity, and there was no late Grade 2 or greater GI toxicity experienced in the study. A

total of 41.7%, 35.4% and 2.1% of subjects experienced acute Grade 1, Grade 2 and Grade 3 genitourinary (GU) toxicity, respectively. There was no Grade 4 acute GU toxicity experienced in the study. Late Grade 1 and Grade 2 GU toxicity was experienced in 17.0% and 2.1% of subjects, respectively and no late Grade 3 or greater GU toxicity was reported. Vienna Rectoscopy Scale (VRS) score of 0 was reported for 71% of subjects, and 1 subject (2%) had Grade 3 telangiectasia. No evidence of ulceration, stricture or necrosis was noted at 12 months. ~~The stated purpose of this trial was to "validate and characterize the spatial and dosimetric effects of PEG hydrogel injection in participants undergoing external beam radiotherapy for prostate cancer". The study did not evaluate participant-centered outcomes. Conclusions were limited by the small size of the study and the lack of a control group. Generalizability is limited by the fact that clinical and demographic characteristics of the subjects were not reported. The authors noted "clinical validation of reduced toxicity in a randomized comparison of intensity-modulated radiotherapy with or without hydrogel is warranted."~~

The largest published peer-reviewed study involving the use of the SpaceOAR device was reported by Mariados and colleagues (2015). This pivotal manufacturer sponsored, prospective, multicenter, single-blind, randomized, controlled trial (RCT) involved 222 subjects with clinical stage T1 or T2 prostate cancer who were randomized in a 2:1 fashion to receive image-guided IMRT (79.2 Gy in 1.8-Gy fractions) either with (n=149) or without (n=73) placement of the SpaceOAR system and were followed for 15 months. Individuals with extracapsular extension were excluded from the study, the authors cited the theoretical risk of pushing posterior extracapsular disease farther from the prostate during RT. The authors reported that perirectal spaces were 12.6 ± 3.9 mm and 1.6 ± 2.0 mm in the spacer and control groups, respectively. Neither group reported any device-related adverse events, rectal perforations, serious bleeding, or infections. The use of SpaceOAR was reported to have resulted in significant reduction in mean rectal V70 when comparing treatment plans with and without the device in place (12.4% to 3.3%, p<0.0001). Acute rectal adverse event rates were similar between groups, with the exception that significantly fewer spacer group subjects reported experiencing rectal pain ~~(p=0.02)~~. Significant benefits were reported in the spacer group with regard to late (3-15 months) rectal toxicity severity, with a 2.0% and 7.0% late grade 1 rectal toxicity incidence in the spacer and control groups, respectively ~~(p=0.04)~~ and no late rectal toxicity greater than grade 1 in the spacer group. At 15 months, 11.6% and 21.4% of spacer and control subjects, respectively, experienced 10-point declines in bowel quality of life. ~~MRI scans at 12 months verified spacer absorption. Limitations of this study include a follow-up period which is inadequate to evaluate late gastrointestinal toxicities of greater than 2, as the median time to onset for these toxicities is 17 months.~~

In 2017, this same group reported the results of an extension study involving 46 control group subjects and 94 SpaceOAR subjects (63% of the original cohort reported at 15 months for both groups) (Hamstra, 2017). No significant differences were reported for the mean follow-up times between groups ~~(p>0.05)~~. With regard to the

volume of the rectum treated to all volumes of V50 to V80, the SpaceOAR group received a significantly smaller volume (p<0.001). For V50 a 54% relative reduction was found, 21% for controls versus 10% for SpaceOAR subjects. The relative reduction at V70 was 79% (10% versus 2%, respectively) and at V80 96% (4% versus 0.1%, respectively). No dosimetry differences were reported for the bladder, bladder wall or bladder/bladder wall within 1 or 2 cm of the prostate. The 3-year incidence of grade ≥ 1 rectal toxicity (9.2% versus 2.0%; p=0.028) and grade ≥ 2 rectal toxicity (5.7% versus 0%; p=0.012) were significantly lower in the SpaceOAR group versus control groups. The rate of grade ≥ 1 urinary incontinence was also significantly lower in the SpaceOAR group (15% versus 4%; p=0.046), but no difference in grade ≥ 2 urinary toxicity was found (7% versus 7%; p=0.7).

In 2018, Hamstra and associates reported on the results of a secondary analysis regarding the sexual quality of life in those individuals who participated in the 2015 Mariados RCT (Mariados, 2015). Prior analyses had shown that while there was lower penile bulb radiation dose with spacer use, there was no difference in average sexual quality of life (QOL) between the spacer and control arms. The authors of the analysis noted that the impact of the spacer on sexual function may have been masked as nearly 60% of the participants had moderate to severe sexual dysfunction at baseline. Approximately 41% (88/222) of men were categorized as having adequate sexual QOL at baseline. When comparing individuals with better baseline sexual QOL scores, the spacer arm reported higher overall sexual scores (spacer 58 [± 24.1] versus the control arm 45 [± 24.4]; p=0.07). These results did not reach statistical significance, but did reach threshold minimally clinically important difference (MID). At 3 years, more men in the spacer group versus the control group self-reported "erections sufficient for intercourse" (control 37.5% versus spacer 66.7%, p=0.046), however that difference was not statistically significant. The authors noted that the small number of individuals with baseline adequate sexual function limited the ability of this analysis to detect differences.

Pinkawa and colleagues (2017a) published the results of a prospective cohort study of 167 subjects with prostate cancer treated with SpaceOAR and either IMRT or volumetric-modulated arc therapy (VMAT). The subjects were asked to complete the Expanded Prostate Cancer Index Composite (EPIC) QOL questionnaire at 2 months post-treatment and then at a median of 17 months. The authors noted that the SpaceOAR group received a significantly higher dose of radiation to the planning target volume compared to the control group (p<0.01). At the last data collection point (> 12 months) treatment of bowel symptoms and endoscopic examinations were significantly lower in the SpaceOAR group compared to the control group (0% versus 11%; p<0.01 and 3% versus 19%; p<0.01; respectively). No differences in acute toxicity were reported. In the SpaceOAR group, mean bowel function scores did not change significantly, whereas control subjects reported a mean decrease of greater than 5 points at 1 year after radiation therapy (RT) compared to baseline (p<0.01). The utility of these results in evaluating the efficacy of rectal spacers is limited by a lack of blinding or randomization. Participant and provider preference determined who

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~~received hydrogel spacer injections. This raises concern about possible selection and observer biases. In addition, subjects self-reported treatments and interventions provided to address bowel problems after their radiation treatment. Larger studies with longer follow-up and more reliable objective outcomes are needed to better evaluate outcomes~~.

Fischer-Valuck (2017) published the results of a prospective cohort study of 149 subjects undergoing radiotherapy with SpaceOAR. The authors' investigation was focused on the correlation of spacer symmetry with rectal dose reduction, as well as rectal wall infiltration ~~(RWI)~~ to acute and late toxicity. They reported that SpaceOAR was symmetrically placed at midline for 71 (47.7%) subjects at the prostate mid-gland as well as 1 cm superior and inferior to mid-gland. The remaining 78 (50.9%) subjects had some level of asymmetry. However, only 2 (1.3%) had far lateral distribution > 2 cm. It was noted that as SpaceOAR placement became more asymmetric, the level of rectal dose reduction relative to their control plans decreased. However, all but the most asymmetrical 1.3% of subjects had significant rectal dose reduction ~~($p<0.05$)~~. Rectal wall infiltration with SpaceOAR was reported in 9 (6.0%) subjects. No correlation between rectal wall infiltration and procedure-related adverse events or acute/late rectal toxicity was reported.

In an industry supported systematic review and meta-analysis, Miller and associates (2020) evaluated the association between perirectal spacer use during radiotherapy and clinical outcomes. The study included seven studies which involved 486 individuals who received a hydrogel spacer and 525 controls. The control group was comprised of potential participants who were not eligible for spacer application due to contraindications or comorbidities~~-~~. The analysis also included data from a study comparing the effectiveness of a hydrogel spacer to balloon spacers. There was no difference between the groups in regards to risk of early grade 2 or higher rectal toxic effects or in changes in bowel-related QOL at 3 months. The hydrogel spacer group was associated with a 77% reduction in grade 2 or higher risk of late rectal toxic effects and a lower risk of rectal toxic effects of any severity at any point in time. The hydrogel group also reported a higher bowel-related QOL in late follow-up, however, this comparison included data from only two studies. ~~The authors note that the analysis included data from a study comparing the effectiveness of a hydrogel spacer to balloon spacers. This study also contained a no-spacer arm of the trial, comprised of potential participants who were not eligible for spacer application due to contraindications or comorbidities. This particular study was not designed to evaluate hydrogel spacers against no spacer and the no spacer group does not appear to be a valid comparator group. The authors noted that the results of this analysis were limited by a lack of randomization and blinding in most studies, attrition, insufficient trial lengths to evaluate late toxicity, and missing data relating to outcomes of interest.~~

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In 2017, Jones and others reported the results of two parallel cohort studies involving subjects being treated for prostate cancer with stereotactic body radiotherapy. In one study subjects were treated using a rectal balloon (n=36) and in the other, with SpaceOAR (n=36). The SpaceOAR group achieved significant dosimetric superiority over the rectal balloon with respect to the maximum dose to the rectum (42.3 versus 46.2 Gy~~, p<0.001~~), dose delivered to 33% of the rectal circumference (28 versus 35.1 Gy~~, p<0.001~~), and absolute volume of rectum receiving 45 Gy (V45Gy), V40Gy, and V30Gy (0.3 versus 1.7 cc, 1 versus 5.4 cc, and 4.1 versus 9.6 cc, respectively~~; p<0.001 in all cases~~). No significant differences between the 2 groups with respect to the V50Gy of the rectum or the dose to 50% of the rectal circumference was reported ~~(p=0.29 and p=0.06, respectively)~~. The V18.3 Gy of the bladder was significantly larger with the rectal balloon (19.9 versus 14.5 cc~~, p=0.003~~). The authors concluded that the rectal balloon did not outperform the injectable spacer gel in any measured rectal dose parameter. While the study evaluated the relative sparing effects of each device on the rectum, it did not address clinical outcomes related to the use of these devices, such as early or late toxicities.

The National Comprehensive Cancer Network (NCCN) Clinical Practice Guidelines for prostate cancer (V 2.2021) includes radiation therapy general principles, noting:

> Ideally, the accuracy of treatment should be verified by daily prostate localization with any of the following: techniques of IGRT using CT, ultrasound, implanted feducials, or electromagnetic targeting/tracking. Endorectal balloons may be used to improve prostate immobilization. Biocompatible and biodegradable perirectal spacer materials may be implanted between the prostate and rectum in patients undergoing external radiotherapy with organ-confined prostate cancer in order to displace the rectum from high radiation dose regions. A randomized phase III trial demonstrated reduced rectal bleeding in patients undergoing the procedure compared to controls. Retrospective data also support its use in similar patients undergoing brachytherapy. Patients with obvious rectal invasion or visible T3 and posterior extension should not undergo perirectal spacer implantation."

The NCCN panel also notes that spacer implantation may be associated with rare complications such as rectum perforation and urethral damage.

There are multiple prospective studies addressing the ~~Many other smaller and less rigorous studies have been published addressing the~~ use of SpaceOAR and showing reduced radiation exposure and rectal and GI toxicities (Chao, 2018a; Chao, 2019b; Chao, 2019; Hedrick, 2017a and 2017b; Juneja, 2015; Pinkawa, 2011; Pinkawa, 2017b; Ruggieri, 2015; Schörghofer, 2019; Te Velde, 2019; van Gysen, 2014; Whalley, 2016; Wilton, 2017; Wu,

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2018). There is a lack of prospective, randomized controlled studies with medium- to long-term follow-up which focus on patient-oriented outcomes. However, hypofractionated radiation therapy and stereotactic body radiotherapy are intensive RT regimens associated with substantially increased risk for GI and GU side effects. Perirectal spacers have been shown to reduce radiation doses to the colon and use of perirectal spacers are generally accepted within the medical community to result in less rectal bleeding and other side effects. ~~Unfortunately the data from these studies is significantly hampered by their methodological flaws, which may include small sample size, lack of control group, absence of blinding, etc. Additional data from prospective, randomized controlled studies with medium- to long-term follow-up which focus on patient-oriented outcomes in addition to reductions in rectal and GI radiation dosages would be helpful to fully understand the benefits and hazards related to use of the SpaceOAR system.~~

Brachytherapy

Kahn and colleagues (2020) evaluated the dosimetric impact and toxicity levels associated with a bioabsorbable hydrogel rectal spacer injected during low-dose-rate (LDR) prostate brachytherapy. Individuals undergoing LDR for prostate cancer received concurrent hydrogel spacer implantation (n=40) and were compared to individuals who did not have a hydrogel spacer implanted (n=40). Individuals with intermediate- and high-risk prostate cancer w~~h~~ere eligible to receive~~d~~ EBRT at their physician's discretion. The average distance between the prostate and rectum with the addition was significantly increased in the spacer group (13.9mm) compared to the control group (6.5mm). At 1 month post-procedure, the rectal grade 1 toxicity was 12.5% in the hydrogel group and 17.5% in the control group. At 1 and 2 years, there was no difference in rectal toxicities between the groups. The authors note that the clinical benefit of hydrogel spacer use during LDR therapy is~~n~~ not clear at a time when the careful placement of permanently implanted seeds is guided by modern ultrasound and treatment planning.

In 2018, a retrospective review by Taggar and associates reported on the impact of rectal hydrogel spacers on dosimetry and acute rectal toxicity in LDR brachytherapy. Individuals who had a spacer placed immediately following Pd-103 seed-implantation (n=74) were compared to a cohort of individuals who did not receive a spacer (n=136). The spacer cohort included those who received brachytherapy as a monotherapy (initial or salvage) or in combination with EBRT. Implantation of the spacer resulted in a median 11.2 mm distance between the prostate and the rectum. There was a significant improvement in all rectal dosimetric parameters in the spacer group compared to the control group. Acute GI toxicities were reported in 10.8% (8/74) of the spacer group compared to 13.2% (18/136) of the control group. At the first post-treatment follow-up, 7 individuals in the spacer group reported grade 1 rectal toxicity. The small retrospective review of a heterogeneous population represents the experience of a limited number of researchers.

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The current evidence is inconclusive regarding hydrogel spacers and brachytherapy due to the limitations in the published studies: small size, retrospective design, limited follow-up and heterogeneous population (Beydoun, 2013; Strom, 2014; Yeh, 2016). These studies are not designed to evaluate the clinical, patient-oriented benefits of spacers in the population undergoing brachytherapy to treat prostate cancer. Further studies are needed to fully assess the benefits related to the use of perirectal spacers during brachytherapy.

Other Products

Other products have been investigated for the same indication as SpaceOAR. One such product is DuraSeal®™ (Integra Lifesciences Corp,~~Covidien~~, Princeton, NJ~~Mansfield, MA~~), a polyethylene glycol hydrogel which received FDA approval in 2005 as an adjunct to sutured dural repair during spinal surgery. A few studies have been published addressing the use of DuraSeal during prostate radiotherapy.

Strom (2014) reported on a nonrandomized controlled trial involving 200 subjects with clinically localized prostate cancer who received high-dose rate brachytherapy with or without intensity modulated radiation therapy. Subjects received treatment either with (n=100) or without (n=100) insertion of DuraSeal into the anterior perirectal fat between the prostate and rectum. The authors reported a DuraSeal implantation success rate of 100%. They also reported that implantation of DuraSeal significantly increased the prostate-rectal separation (12 ± 4 mm with versus 4 ± 2 mm without DuraSeal~~, p<0.001~~) and significantly decreased the mean rectal D2 mL (47 ± 9% with versus 60 ± 8% without DuraSeal~~, p<0.001~~). It was noted that implantation of DuraSeal decreased rectal doses regardless of body mass index (BMI). Subjects were followed for a median of 8.7 months. No data were presented regarding adverse events, including rectal toxicity.

In 2016, another study was published addressing the use of DuraSeal (Yeh, 2016). This non-controlled case series study involved 326 subjects with prostate carcinoma who underwent combination high-dose rate brachytherapy and external beam radiotherapy. All subjects had DuraSeal implanted into the anterior perirectal fat space prior to radiotherapy. The median follow-up was 16 months. The authors stated that the mean anterior-posterior separation achieved was 1.6 cm (standard deviation [SD] =0.4 cm). Rates of acute Grade 1 and 2 rectal toxicity were 37.4% and 2.8%, respectively. No acute Grade 3/4 toxicities were reported. Rates of late Grade 1, 2, and 3 rectal toxicity were 12.7%, 1.4%, and 0.7%, respectively. There were no late Grade 4 toxicities. ~~The authors concluded that DuraSeal is safe and well tolerated, and acute and chronic rectal toxicities were low despite aggressive dose escalation~~The limitations of this study included its single arm, retrospective design and short-term follow-up. ~~.~~

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A small nonrandomized controlled trial involving 20 subjects undergoing proton beam therapy with (n=12) or without (n=8) DuraSeal was published by Chung in 2016. However, this small study provides little generalizable information regarding the efficacy of this product.

Another product, Rectafix™ (Scanflex Medical AB), has been studied for the same indications as SpaceOAR. Wilton (2017) described a retrospective study of 45 subjects from the PROMETHEUS trial who received a total dose (TD) of 19 or 20 Gy in two fractions followed by 46 Gy in 23 fractions. This study compared the use of Rectafix (n=35) versus SpaceOAR (n=10). Based on the results of several subanalyses, the authors reported that Rectafix versus SpaceOAR demonstrated lower mean doses at 9 out of 11 measured intervals (p=0.0012). However, they noted that although dose levels were in favor of Rectafix, in absolute terms the differences were small (2.6-9.0%). The findings of this study are weak due to the small subject pool, and retrospective methodology. Further large, well-designed studies are warranted to investigate the safety and efficacy of this product. ~~Finally, at this time Rectafix is not currently approved by the FDA.~~

~~*All Devices*~~

~~In 2018 the Cochrane Library published a new report titled "Interventions to reduce acute and late adverse gastrointestinal effects of pelvic radiotherapy for primary pelvic cancers" (Lawrie, 2018). This report looked at the use of perirectal spacers and concluded that. "Low-certainty evidence on balloon and hydrogel spacers suggests that these interventions for prostate cancer RT may make little or no difference to GI outcomes."~~

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> ~~Ideally, the accuracy of treatment should be verified by daily prostate localization with any of the following: techniques of IGRT using CT, ultrasound, implanted feducials, or electromagnetic targeting/tracking. Endorectal balloons may be used to improve prostate immobilization. Perirectal spacer materials may be implanted between the prostate and rectum in patients undergoing external radiotherapy with organ confined prostate cancer in order to displace the rectum from high radiation dose regions. A randomized phase III trial demonstrated reduced rectal bleeding in patients undergoing the procedure compared to controls. Retrospective data also support its use in similar patients undergoing brachytherapy. Patients with obvious rectal invasion or visible T3 and posterior extension should not undergo perirectal spacer implantation."~~

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~~The NCCN panel also notes that spacer implantation may be associated with rare complications such as rectum perforation and urethral damage.~~

~~The Canadian Agency for Drugs and Technologies in Health (CADTH) 2019 report on the use of hydrogel spacers in the treatment of prostate cancer noted that the current evidence basis is not adequate to evaluate the benefits of spacers and that additional high-quality studies would be useful. The report also notes:~~

> ~~There are also other no-spacer options available to reduce the adverse effects of radiotherapy for prostate cancer patients, such as the choice of radiotherapy, high-fiber diet, and radiation dose optimization. Consideration of these alternatives may also be important to improve outcomes and quality of life for prostate cancer patients.~~

Background/Overview

Prostate cancer is the most common cancer among U.S. males. In 202~~1~~0, an estimated ~~191~~248,~~59~~30 new cases of prostate cancer will be diagnosed and approximately 3~~4~~3,~~1~~330 deaths will be from prostate cancer. ~~Approximately~~ More than 3.1 million men are living with a diagnosis of prostate cancer (ACS, 202~~1~~0).

Radiotherapy for the treatment of prostate cancer is very common, being one of the most used treatment methods available, supported by national guidelines from an array of authoritative organizations. The use of highly conformal radiation techniques allows precise treatment of the prostate while minimizing exposure of adjacent tissue. However, due to the close proximity of surrounding organs, the risk ~~of radiation~~of radiation induced toxicity of the tissue adjacent to the prostate remains. The risk of unintentional exposure can be reduced by daily prostate localization to improve treatment accuracy. Another method proposed to prevent that from occurring is to create space between those tissues and the prostate, and one method of doing this involves the injection of a polyethylene glycol hydrogel into the space between the rectum and prostate. ~~As stated above,~~ SpaceOAR is the only product currently approved by the FDA for such purposes.

SpaceOAR is a biodegradable polyethylene glycol hydrogel that is injected as a liquid between the prostate and rectum under ultrasound guidance. Once injected, the liquid solidifies within seconds into a hydrogel that pushes the anterior rectal wall away from the prostate, increasing the peri-rectal space. SpaceOAR is completely resorbed by the body over time. ~~While studies support that the use of peri-rectal hydrogel spacers do increase the perirectal space, these spacers are unable to fix the pelvic organs and reduce intra-fractional prostate motion. These spacers are unable to control rectal filling (Ghaffari, 2020).~~ This is in contrast to endorecal balloons or rectal retractors.
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These devices are used to fix the rectal volume and position, which expands the rectal wall and results in a smaller planning target volume, ultimately sparing more portions of the wall (Ghaffari, 2020).

Other polyethylene glycol hydrogel products have been proposed for use in decreasing rectal toxicity during prostate radiotherapy. One such product is DuraSeal, which received FDA approval in 2005 as an adjunct to sutured dural repair during spinal surgery.

Definitions

FDA Cleared Device: A medical device which the FDA has determined to be substantially equal to another legally marketed device. Once the FDA has approved a device, a 510(k) approval is given.

Hypofractionated Radiation Therapy: Therapy in which the total dose of radiation is divided into larger doses compared to standard radiation doses, resulting in a shorter treatment period.

Stereotactic Body Radiation Therapy: External radiation treatment in which the total radiation dose is divided into small doses and delivered precisely into the tumors, sparing the surrounding tissue. Also known as SABR, SBRT or stereotactic ablative body radiation therapy.

Coding

The following codes for treatments and procedures applicable to this document are included below for informational purposes. Inclusion or exclusion of a procedure, diagnosis or device code(s) does not constitute or imply member coverage or provider reimbursement policy. Please refer to the member's contract benefits in effect at the time of service to determine coverage or non-coverage of these services as it applies to an individual member.

When services may be ~~are Investigational and Not~~ Medically Necessary when criteria are met:
~~For the following procedure codes; or when the code describes a procedure indicated in the Position Statement section as investigational and not medically necessary.~~

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

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ICD-10 Diagnosis

	~~All diagnoses~~
C61	Malignant neoplasm of prostate
D07.5	Carcinoma in situ of prostate
Z51.0	Encounter for antineoplastic radiation therapy
Z85.46	Personal history of malignant neoplasm of prostate

When services are Investigational and Not Medically Necessary:
For the procedure and diagnosis codes listed above when criteria are not met, or for all other diagnoses not listed.

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Index

The use of specific product names is illustrative only. It is not intended to be a recommendation of one product over another, and is not intended to represent a complete listing of all products available.

Document History

Status	Date	Action
Revised	05/13/2021	Medical Policy & Technology Assessment Committee (MPTAC) review. Revised position statement from perirectal spacers are investigational and not medically necessary in all cases to statement that perirectal spacers are medical necessary for hypofractionated radiation therapy or stereotactic body radiotherapy when criteria are met. Added investigational and not medically necessary statement when criteria are not met and for all other indications. Updated Rationale, Coding and References sections.
Reviewed	02/11/2021	~~Medical Policy & Technology Assessment Committee (~~MPTAC~~)~~ review. Updated Rationale, Background, References and Description sections.
Reviewed	02/20/2020	MPTAC review. Updated Rationale, Background, References and Description sections.
Reviewed	06/06/2019	MPTAC review. Updated Rationale and References sections.
Reviewed	07/26/2018	MPTAC review.

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Reviewed	07/18/2018	Hematology/Oncology Subcommittee review. Updated Rationale and References sections.
Reviewed	11/02/2017	MPTAC review.
Reviewed	11/01/2017	Hematology/Oncology Subcommittee review. The document header wording updated from "Current Effective Date" to "Publish Date." Updated Rationale and References sections. Updated Coding section with 01/01/2018 CPT changes; removed 0438T deleted 12/31/2017.
Revised	11/03/2016	MPTAC review.
Revised	11/02/2016	Hematology/Oncology Subcommittee review. Revised title. Clarified MN statement. Updated Rationale and Reference sections.
New	05/05/2016	MPTAC review.
New	05/04/2016	Hematology/Oncology Subcommittee review. Initial document development.