Hydrogel spacer use during radiotherapy for prostate cancer

Clinical Policy ID: CCP.1476

Recent review date: 11/2025

Next review date: 3/2027

Policy contains: hydrogel spacer; polyethylene glycol; radiotherapy; prostate cancer; rectum; brachytherapy

Coverage policy

A hydrogel spacer is clinically proven and, therefore, may be medically necessary for reducing exposure of the rectum to radiotherapy in members with localized prostate cancer (American Brachytherapy Society [Garant, 2025]; American Urological Association/American Society for Radiation Oncology [Eastham, 2022]; National Comprehensive Cancer Network, 2025).

Hydrogel spacers are considered clinically proven when utilized with the following radiotherapy modalities (Eastham, 2022; Garant, 2025; NCCN, 2025):

- External beam radiation therapy (photon or proton), inclusive of conventional fractionation, moderate hypofractionation, and ultra-hypofractionation.
- Low-dose-rate (permanent seed brachytherapy monotherapy.

Hydrogel spacers are investigational/not clinically proven and, therefore, not medically necessary for the following (Garant, 2025):

- High-dose-rate brachytherapy monotherapy.
- Combination brachytherapy with external beam radiation.
- All other uses of a hydrogel spacer in prostate care.

Limitations

Hydrogel spacer implantation is contraindicated in the following situations (Garant, 2025; NCCN, 2025):

- Members with grossly apparent true posterior extraprostatic extension.
- High suspicion of tumor abutment or direct invasion of the rectum.
- Active abdominal or pelvic infection.
- Absence of rectum (prior proctectomy).
- Untreated rectal malignancy.

Alternative covered services

Endorectal balloon.

Background

Prostate cancer is the most commonly diagnosed cancer among American males, with an estimated 299,010 new cases and 35,250 deaths in 2024 (American Cancer Society, 2024).

Patients with prostate cancer can be treated with external beam radiotherapy (including intensity-modulated radiotherapy or stereotactic body radiation therapy), or with hypofractionated radiotherapy, proton beam therapy, and brachytherapy. The proximity of the rectum to the prostate gland raises the risk of rectal toxicity after radiation therapy for prostate cancer, prompting research on ways to minimize this adverse effect (Afkhami Ardekani, 2020; Forero, 2018).

Various materials, including collagen, polyethylene glycol hydrogel spacers, and absorbable balloons have been evaluated to reduce rectal radiation exposure. Radioprotective spacers, first reported 30 years ago for radiotherapy of tongue and abdominal cancers, have been developed for prostate cancer (Tang, 2018).

The U.S. Food and Drug Administration (2024) has issued 510(k) premarket approval to several absorbable perirectal spacers: SpaceOAR® Hydrogel System and the SpaceOAR Vue™ Hydrogel (formerly Augmenix Inc., Bedford, Massachusetts, now Boston Scientific Corp., Marlborough, Massachusetts); Barrigel Injectable Gel (Palette Life Sciences, Santa Barbara, California); and the BioProtect Balloon Implant™ System (BioProtect, Ltd., Philadelphia, Pennsylvania). As a minimally invasive procedure, each spacer is implanted by injecting a bioabsorbable gel through a dedicated delivery system under transrectal ultrasound guidance. These radioprotective spacers are intended to temporarily position the anterior rectal wall away from the prostate during radiotherapy for prostate cancer, thereby reducing the radiation dose delivered to the anterior rectum. The gel is generally absorbed into the system within a few months after implantation.

Another product used in hydrogel spacer procedures for prostate cancer is DuraSeal® (Covidien, Mansfield, Massachusetts). It has no regulatory approval for this use, but is used off-label, having been approved in 2005 as an adjunct to sutured dural repair during spinal surgery (Afkhami Ardekani, 2020).

Findings

Across evidence types, findings for hydrogel spacers used during prostate radiotherapy show consistent rectal dose reduction with more variable effects on toxicity and quality of life, and contemporary guidelines adopt this pattern. Professional societies endorse hydrogel spacers for selected patients across external beam and proton modalities and, in some circumstances, brachytherapy, while emphasizing operator experience, imaging guidance, and contraindications such as gross posterior extraprostatic extension. Randomized trials

demonstrate reliable prostate–rectum separation, reduced rectal dose, and lower early rectal toxicity, although effects on late toxicity and broader quality of life remain modest. Observational cohorts extend these conclusions across conventional, moderate, and stereotactic schedules, confirming feasibility and generally favorable gastrointestinal and genitourinary profiles but identifying mixed urinary and sexual outcomes that differ by modality and treatment combination. Systematic reviews and meta-analyses consistently report high technical success, substantial dose reduction, and low complication rates, though the strongest evidence remains concentrated in hydrogel use during external beam radiotherapy. Post-marketing surveillance identifies a low overall rate but clinically meaningful range of serious complications, reinforcing guideline directives for careful patient selection and meticulous technique.

Guidelines

The American Urological Association/ American Society for Radiation Oncology [Eastham, 2022]) and the National Comprehensive Cancer Network states that biocompatible, biodegradable spacers may be implanted between the prostate and rectum in patients undergoing radiation therapy to the prostate to displace the rectum from high-dose regions; placement should be by moderate- to high-volume operators, and extra caution is advised in reirradiation. Gross posterior extraprostatic extension is a contraindication, while high-risk disease without posterior extension is not (National Comprehensive Cancer Network, 2025). For brachytherapy, the National Comprehensive Cancer Network notes that spacers may be used when efforts to improve cure or reduce toxicity due to anatomic geometry or other patient factors are insufficient. American Brachytherapy Society consensus supports spacers for external beam photon therapy, proton therapy, and low dose rate brachytherapy monotherapy, with no consensus for high dose rate monotherapy or for combined external beam therapy with a brachytherapy boost (National Comprehensive Cancer Network, 2025; American Brachytherapy Society, 2025).

Technical execution and imaging affect outcomes. The National Comprehensive Cancer Network recommends placement by moderate- to high-volume operators and advises caution in reirradiation. The American Brachytherapy Society recommends pelvic magnetic resonance imaging after difficult placement or when rectal wall infiltration is suspected, with endorectal ultrasound acceptable if magnetic resonance imaging is unavailable. The 2022 American Urological Association/ American Society for Radiation Oncology guideline on clinically localized prostate cancer highlights the evidence from a key phase III randomized trial which found that, for patients receiving conventionally fractionated radiation (79.2 Gy), the use of a rectal spacer resulted in improvements in low-grade rectal toxicity and better bowel health-related quality of life. The guideline also explicitly states that the utility of this technology has not been established in prospective randomized trials for patients undergoing hypofractionated or ultra-hypofractionated radiation (Eastham, 2022). This aligns with other findings that randomized trials support polyethylene glycol hydrogel in conventional fractionation and non-animal stabilized hyaluronic acid gel in moderate hypofractionation (American Brachytherapy Society, 2025).

Evidence reviews

The evidence from the following systematic reviews consists of retrospective, observational studies of generally low quality and one randomized controlled trial. The majority of studies examined polyethylene glycol hydrogel spacers (SpaceOAR and DuraSeal). The characteristics of study participants were not always well described, but men with clinically localized prostate cancer were included. The randomized controlled trial provides some guidance on additional selection criteria in men who underwent prostate image-guided intensity modulated radiation therapy: prostate volumes ≤ 80 mL, no extracapsular extension, and no prior radiation or surgery (Mariados, 2015). However, these criteria may not be applicable to recipients of other types of radiation therapy or therapy protocols.

Hydrogel spacers increase the distance between the prostate and rectum, reduce rectal radiation exposure, and compare favorably to endorectal balloons in reducing prostate motion. The randomized controlled trial (Mariados,

2015) with long term follow-up demonstrated significant reductions in late gastrointestinal and genitourinary toxicities, and observational studies generally confirm these findings across a range of radiation therapy modalities. The effect of hydrogel spacers on quality of life, oncologic outcomes, and other adjacent organ toxicity is less clear.

Implantation is feasible and well-tolerated with a favorable safety profile. The overall complication rate is low, but serious complications have been reported outside of clinical studies. For example, of the more than 206,000 SpaceOAR and SpaceOAR Vue devices sold from 2015 to 2022, one analysis examined 981 events reported to the Manufacturer and User Facility Device Experience database from January 2015 to May 2023, along with other manufacturer data. Device malfunction (e.g., device positioning problem) and patient injuries (e.g., device-related abscesses, rectourethral fistulas, and rectal ulcers) were the most common post-approval complications and adverse events. In total, 470 (50.2%), 344 (36.7%), 123 (13.1%) of the adverse events were Common Terminology Criteria for Adverse Events grade 1, 2, and 3 or higher, respectively (Millot, 2024).

A systematic review of eight studies of 780 males treated with stereotactic body radiation therapy for early-stage prostate cancer revealed that compared to no spacer, SpaceOAR reduced the radiation to the rectum by 29% to 56% regardless of radiation dose. Freedom from biochemical failure ranged from 96.4% to 100% after a median follow-up of 16 months (Payne, 2021).

A systematic review of eight studies of patients undergoing external beam radiation therapy for localized prostate cancer found SpaceOAR reduced rectal radiation dose volume. Four studies analyzed toxicity; SpaceOAR decreased acute Grade 1 diarrhea in one study and decreased late Grade 1 and Grade ≥ 2 rectal toxicities in two others. One study reported fewer large declines in bowel quality of life at three years among SpaceOAR patients, but another reported no benefit after five years (Babar, 2021).

A systematic review of 19 studies (n = 3,622) revealed SpaceOAR significantly reduced rectal radiation dose, regardless of type of radiation therapy. Use of the device also reduced gastrointestinal and genitourinary toxicities. Only one of the 19 studies was randomized (Armstrong, 2021).

A systematic review and meta-analysis of seven studies (one randomized, n = 1,011) of prostate cancer compared 486 subjects who received a hydrogel spacer prior to radiotherapy to 525 who did not. Mean follow-up was 26 months. The success rate of placement was 97.0%. Procedural complications were observed in less than 10% of patients and were mild and transient. The treatment group received 66% less v70 rectal irradiation versus controls (3.5% and 10.4%, P = .001). The risk of grade 2 or higher rectal toxic effects was similar in early follow-up (4.5% and 4.1%, P = .38), but was 77% lower in the treatment group in late follow-up (1.5% vs 5.7%, P = .05). Changes in bowel-related quality of life were similar (P = .92) but greater in the hydrogel spacer group in late follow-up (P < .001) (Miller, 2020).

Compared with the endorectal balloon, polyethylene glycol hydrogel spacers significantly reduced rectal dose and toxicity without influencing prostate immobilization in patients receiving external beam radiation therapy and brachytherapy (Afkhami Ardekani, 2020, 2021).

Results of two recent observational studies with long term follow-up provide conflicting results regarding the effect of hydrogel spacers on quality of life after prostate radiation therapy. In one study, hydrogel spacer use was associated with better sexual quality of life, less measurable decline in sexual quality of life, and higher rates of adequate erectile function (Seymour, 2023).

Another study found patients undergoing low-dose-rate brachytherapy alone experienced no significant improvement in urinary, bowel or sexual quality of life when using a hydrogel spacer. In patients undergoing low-dose-rate brachytherapy in combination with intensity-modulated radiotherapy, a hydrogel spacer did significantly improve bowel quality of life, but not sexual or urinary quality of life (Nakia, 2024).

In 2025, we found A meta-analysis by Miszczyk (2025) that included three randomized controlled trials with a total of 645 patients, as well as a qualitative summary of 22 non-randomized trials comprising an additional 1,140 patients. The meta-analysis of the randomized trials found that spacers were associated with a significant decrease in early grade two or higher rectal adverse events, with a number needed to treat of 26 to prevent one event. However, it did not find a statistically significant reduction in late moderate-grade events, with a corresponding number needed to treat of 135. A broader systematic review by Lippens (2025) analyzed 30 prospective randomized and non-randomized clinical trials to assess efficacy and safety. This review highlighted a favorable safety profile, reporting an overall complication rate of 0.96 percent for hydrogel spacers. It noted that no grade four or five gastrointestinal toxicity was reported in any of the included trials, concluding their use was associated with improved long-term bowel quality of life. We added specific radiotherapy modalities including hypofractionated treatments based on 2025 guidelines (Garant, 2025; NCCN, 2025), specified investigational uses for brachytherapy combinations, and added detailed clinical contraindications beyond posterior extension.

References

On October 20, 2025, we searched PubMed and the databases of the Cochrane Library, the U.K. National Health Services Centre for Reviews and Dissemination, the Agency for Healthcare Research and Quality, and the Centers for Medicare & Medicaid Services. Search terms were “hydrogel spacer,” “polyethylene glycol,” “radiotherapy,” “brachytherapy,” “prostate cancer,” and “rectum.” We included the best available evidence according to established evidence hierarchies (typically systematic reviews, meta-analyses, and full economic analyses, where available) and professional guidelines based on such evidence and clinical expertise.

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Policy updates

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