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Approval and implementation dates for specific health plans may vary. Please consult the applicable health plan for more details.

Clinical Appropriateness Guidelines

Radiation Oncology

Appropriate Use Criteria: Perirectal Hydrogel Spacer for Prostate Radiotherapy

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Description and Application of the Guidelines

The Carelon Clinical Appropriateness Guidelines (hereinafter “the Carelon Clinical Appropriateness Guidelines” or the “Guidelines”) are designed to assist providers in making the most appropriate treatment decision for a specific clinical condition for an individual. The Guidelines establish objective and evidence-based criteria for medical necessity determinations, where possible, that can be used in support of the following:

- To establish criteria for when services are medically necessary
- To assist the practitioner as an educational tool
- To encourage standardization of medical practice patterns
- To curtail the performance of inappropriate and/or duplicate services
- To address patient safety concerns
- To enhance the quality of health care
- To promote the most efficient and cost-effective use of services

The Carelon guideline development process complies with applicable accreditation and legal standards, including the requirement that the Guidelines be developed with involvement from appropriate providers with current clinical expertise relevant to the Guidelines under review and be based on the most up-to-date clinical principles and best practices. Resources reviewed include widely used treatment guidelines, randomized controlled trials or prospective cohort studies, and large systematic reviews or meta-analyses. Carelon reviews all of its Guidelines at least annually.

Carelon makes its Guidelines publicly available on its website. Copies of the Guidelines are also available upon oral or written request. Additional details, such as summaries of evidence, a list of the sources of evidence, and an explanation of the rationale that supports the adoption of the Guidelines, are included in each guideline document.

Although the Guidelines are publicly available, Carelon considers the Guidelines to be important, proprietary information of Carelon, which cannot be sold, assigned, leased, licensed, reproduced or distributed without the written consent of Carelon. Use of the Guidelines by any external AI entity without the express written permission of Carelon is prohibited.

Carelon applies objective and evidence-based criteria, and takes individual circumstances and the local delivery system into account when determining the medical appropriateness of health care services. The Carelon Guidelines are just guidelines for the provision of specialty health services. These criteria are designed to guide both providers and reviewers to the most appropriate services based on a patient’s unique circumstances. In all cases, clinical judgment consistent with the standards of good medical practice should be used when applying the Guidelines. Guideline determinations are made based on the information provided at the time of the request. It is expected that medical necessity decisions may change as new information is provided or based on unique aspects of the patient’s condition. The treating clinician has final authority and responsibility for treatment decisions regarding the care of the patient and for justifying and demonstrating the existence of medical necessity for the requested service. The Guidelines are not a substitute for the experience and judgment of a physician or other health care professionals. Any clinician seeking to apply or consult the Guidelines is expected to use independent medical judgment in the context of individual clinical circumstances to determine any patient’s care or treatment.

The Guidelines do not address coverage, benefit or other plan specific issues. Applicable federal and state coverage mandates take precedence over these clinical guidelines, and in the case of reviews for Medicare Advantage Plans, the Guidelines are only applied where there are not fully established CMS criteria. If requested by a health plan, Carelon will review requests based on health plan medical policy/guidelines in lieu of the Carelon Guidelines. Pharmaceuticals, radiotracers, or medical devices used in any of the diagnostic or therapeutic interventions listed in the Guidelines must be FDA approved or conditionally approved for the intended use. However, use of an FDA-approved or conditionally approved product does not constitute medical necessity or guarantee reimbursement by the respective health plan.

The Guidelines may also be used by the health plan or by Carelon for purposes of provider education, or to review the medical necessity of services by any provider who has been notified of the need for medical necessity review, due to billing practices or claims that are not consistent with other providers in terms of frequency or some other manner.

General Clinical Guideline

Clinical Appropriateness Framework

Critical to any finding of clinical appropriateness under the guidelines for a specific diagnostic or therapeutic intervention are the following elements:

- Prior to any intervention, it is essential that the clinician confirm the diagnosis or establish its pretest likelihood based on a complete evaluation of the patient. This includes a history and physical examination and, where applicable, a review of relevant laboratory studies, diagnostic testing, and response to prior therapeutic intervention.
- The anticipated benefit of the recommended intervention is likely to outweigh any potential harms, including from delay or decreased access to services that may result (net benefit).
- Widely used treatment guidelines and/or current clinical literature and/or standards of medical practice should support that the recommended intervention offers the greatest net benefit among competing alternatives.
- There exists a reasonable likelihood that the intervention will change management and/or lead to an improved outcome for the patient.

Providers may be required to submit clinical documentation in support of a request for services. Such documentation must a) accurately reflect the clinical situation at the time of the requested service, and b) sufficiently document the ordering provider's clinical intent.

If these elements are not established with respect to a given request, the determination of appropriateness will most likely require a peer-to-peer conversation to understand the individual and unique facts that would justify a finding of clinical appropriateness. During the peer-to-peer conversation, factors such as patient acuity and setting of service may also be taken into account to the extent permitted by law.

Simultaneous Ordering of Multiple Diagnostic or Therapeutic Interventions

Requests for multiple diagnostic or therapeutic interventions at the same time will often require a peer-to-peer conversation to understand the individual circumstances that support the medical necessity of performing all interventions simultaneously. This is based on the fact that appropriateness of additional intervention is often dependent on the outcome of the initial intervention.

Additionally, either of the following may apply:

- Current literature and/or standards of medical practice support that one of the requested diagnostic or therapeutic interventions is more appropriate in the clinical situation presented; or
- One of the diagnostic or therapeutic interventions requested is more likely to improve patient outcomes based on current literature and/or standards of medical practice.

Repeat Diagnostic Intervention

In general, repeated testing of the same anatomic location for the same indication should be limited to evaluation following an intervention, or when there is a change in clinical status such that additional testing is required to determine next steps in management. At times, it may be necessary to repeat a test using different techniques or protocols to clarify a finding or result of the original study.

Repeated testing for the same indication using the same or similar technology may be subject to additional review or require peer-to-peer conversation in the following scenarios:

- Repeated diagnostic testing at the same facility due to technical issues
- Repeated diagnostic testing requested at a different facility due to provider preference or quality concerns

- Repeated diagnostic testing of the same anatomic area based on persistent symptoms with no clinical change, treatment, or intervention since the previous study
- Repeated diagnostic testing of the same anatomic area by different providers for the same member over a short period of time

Repeat Therapeutic Intervention

In general, repeated therapeutic intervention in the same anatomic area is considered appropriate when the prior intervention proved effective or beneficial and the expected duration of relief has lapsed. A repeat intervention requested prior to the expected duration of relief is not appropriate unless it can be confirmed that the prior intervention was never administered. Requests for on-going services may depend on completion of previously authorized services in situations where a patient's response to authorized services is relevant to a determination of clinical appropriateness.

Perirectal Hydrogel Spacer for Prostate Radiotherapy

General Information

Radiation Oncology Considerations

Because the anterior wall of the rectum abuts the posterior prostate, radiotherapy for prostate cancer exposes that portion of the rectum to the full dose of radiation delivered to the prostate, which poses the risk of rectal bleeding for months to years after treatment. Modern radiation planning techniques, such as intensity modulated radiation therapy (IMRT), allow significantly higher doses of radiation to be safely delivered to the prostate while maintaining an acceptable risk of late rectal complications by limiting the portion of the rectum treated to full dose. In recent years, attempts to reduce rectal toxicity have focused on increasing the physical distance between the prostate and rectum by injection of a biodegradable hydrogel to push the rectum away from the high dose region to allow additional dose sparing.

The use of an implanted hydrogel spacer between the prostate and rectum has been studied as a way to minimize rectal symptoms during and after definitive radiotherapy for adenocarcinoma of the prostate. There are currently two types of hydrogel spacer. SpaceOAR, is a water based hydrogel spacer and Barrigel is a hyaluronic acid rectal spacer. Both remain in place for approximately 3 months before being absorbed by the body.

External Beam Radiation Therapy

The first randomized controlled trial (RCT) of hydrogel spacer placement was reported by Mariados. It randomly assigned patients 2:1 for either spacer placement or placebo. Study participants had stage T1 or T2 stage prostate cancer without extracapsular extension. A total of 149 patients had the spacer placed prior to radiotherapy and were compared to 73 patients treated without spacer injection. Both groups were treated with image-guided IMRT to a dose of 79.2 Gy in 44 fractions.

The initial report was published in 2015 and showed no significant reduction in rectal adverse events in the first 6 months (34.2% with spacer vs 31.5% without, P = .7). Significant reduction in late (3-15 month) rectal toxicity was associated with spacer placement, with 2% (3 patients) and 7% (5 patients) experiencing grade 1 or greater GI symptoms in the hydrogel and control arms (P = .044), respectively. Urinary toxicity was not significantly different between the groups.

Hamstra et al. subsequently reported 36-month results of a subset of the original trial participants. They reported a 0% grade 2 or higher rectal toxicity with spacer use versus a 5.7% rate without the spacer (P = .012). They also noted a significant reduction in grade 1 urinary incontinence favoring spacer placement (15% vs 4%, P = .046). A subsequent analysis reported an improvement in sexual function with the spacer, but this did not meet statistical significance.

There is a strong secular trend toward the use of shorter courses of external beam radiation therapy to treat low-risk and intermediate-risk prostate cancer. Multiple randomized controlled trials (RCT) of shorter course radiation, also called hypofractionated radiation, have shown equivalent cure rates to conventionally fractionated radiation but with a higher incidence acute rectal toxicity. Given the higher GI toxicity of this regimen, the use of a hydrogel spacer would be most advantageous in this cohort of patients and has become standard of care in this setting.

Stereotactic Body Radiation Therapy

Stereotactic body radiation therapy (SBRT), also termed ultrahypofractionated radiation therapy is an alternative radiation modality to treat low-risk and intermediate risk prostate cancer. Treatment is given in 5 or fewer daily sessions or fractions. Fried et al. reported on the use of a perirectal hydrogel spacer in association with SBRT. The retrospective report demonstrated significant improvement in rectal and penile bulb dosimetry with the use of the spacer in 66 patients compared to 28 patients who had not undergone spacer placement.

A much larger study by Zelefsky and colleagues examined outcomes in 551 patients with low-risk and intermediate-risk prostate cancer treated with SBRT. The treatment consisted of 37.5-40 Gy in 5 fractions directed to the prostate and seminal vesicles. About half of the patients (269/551) received a rectal spacer as this became a standard part of the group's treatment protocol in November 2016. The use of a spacer was associated with a

significant reduction in any late GI toxicity (1% with spacer vs 6% without, P = .010). Spacer placement also significantly reduced late GU toxicity (15% for spacer vs 32% without, P < .001).

Brachytherapy

The use of a hydrogel spacer in the setting of low dose rate (LDR) brachytherapy has been reported by Khan et al. Forty patients who underwent perirectal hydrogel injection were compared to 40 patients who had not undergone spacer placement. Some of the patients also received external beam radiation. There was a reduction in rectal toxicity at 1 month, but no difference in toxicity at either one or 2-year follow-up. This finding was similar to a previous report by Taggar et al. comparing toxicity in 74 patients with spacer placement prior to Pd-103 LDR brachytherapy to a similar cohort without spacers. Similarly, a report by Lin et al. examining non-randomized outcomes of hydrogel spacer use prior to LDR brachytherapy showed reduced rates of grade 1 toxicity but no significant difference in grade 2 or 3 toxicities. Despite improvements in rectal dosimetry, there was no significant improvement in acute rectal toxicity. A recent observational study by Nakai et al found no benefit in urinary, sexual, or hormonal domain scores for hydrogel spacer with LDR brachytherapy alone, but improved bowel QOL for patients who were undergoing LDR brachytherapy with IMRT.

Systematic Reviews

A systematic review of the use of a hydrogel spacer to reduce toxicity during and after radiotherapy for prostate cancer was published by Armstrong et al. This review is more extensive than previous reviews by Miller et al. and the Canadian Agency for Drugs and Technologies in Health (CADTH). In addition to the RCT described above, they reviewed 18 additional spacer studies looking at several radiotherapy techniques. Seven of the 18 studies evaluated hydrogel use with conventionally fractionated IMRT. Two studies examined outcomes when used with SBRT, and one looked at spacer use with proton therapy. Most of the other studies included patients treated with combinations of external beam radiation and brachytherapy.

An updated systematic review on biodegradable hydrogel spacer done by Wong et al. included 3 RCTs, 3 prospective cohorts, and 11 retrospective cohorts. Over 3200 patients were included with 1471 patients who received per-rectal spacer and 1729 who did not use of spacer was associated with lower likelihood of late and early grade 2 or above rectal toxicity. No difference was seen in grade 3 or above GI (acute or late) events. There was also no statistical difference in bowel-related QoL. Perirectal spacer was not associated with negative impact to urinary or sexual QoL either.

Toxicity and Risk

A recent commentary published in Lancet Oncology urged caution in the widespread use of the hydrogel spacer given the small expected benefit and the rising number of reported adverse events associated with the procedure. Despite excellent safety in the small trial, there are a growing number of reports of significant adverse events in real-world use. By examining the FDA Manufacturer and User Facility Device (MAUDE) database, the authors identified 85 reported events. The majority of these could be converted into graded toxicities using Common Terminology Criteria for Adverse Events. Approximately 70% of the events were graded 3, 4, or 5, with about 24% falling into the grade 4 category, including colostomy, anaphylactic events, rectal wall injection, and pulmonary embolism. There was one death. They concluded that critical reflection and careful consideration of the need, toxicity, and benefits of perirectal hydrogel spacer placement should precede any recommendation for its use.

Definitions

Low risk of recurrence (**ALL** must be present to qualify as low risk)

- Stage T1-T2a
- Gleason score of 6
- Prostate-specific antigen (PSA) below 10 ng/mL
- No evidence of metastatic disease

Intermediate risk of recurrence (**ANY** characteristic and without evidence of metastatic disease)

- Stage T2b to T2c
- Gleason score of 7

- PSA 10-20 ng/mL

High risk of recurrence (**ANY** characteristic and without evidence of metastatic disease)

- Stage T3a
- Gleason score 8-10
- PSA greater than 20 ng/mL

Localized disease (ALL must apply)

- T stage of T1-3a (tumor has spread through the capsule on one or both sides but has not invaded the seminal vesicles or other structures)
- N0 (no lymph node involvement)
- No evidence of metastatic disease

Locally advanced disease (**EITHER** must apply)

- Any T status with N1 disease (either no spread to lymph nodes or there has been spread to the regional lymph nodes)
- T3b and above, no distant metastatic disease beyond local lymph nodes

Distant metastatic disease

- Beyond the local lymph nodes

Clinical Indications

Hydrogel Spacer

The use of an implanted hydrogel spacer between the prostate and rectum is medically necessary when primary definitive radiation therapy will be used to treat prostate cancer using any form of external beam radiation therapy (only Photon-based 3D conformal, IMRT, SBRT)

The use of hydrogel spacer is not medically necessary for prostate brachytherapy or proton beam therapy (PBT).

Codes

The following code list is not meant to be all-inclusive. Authorization requirements will vary by health plan. Please consult the applicable health plan for guidance on specific procedure codes.

Specific CPT codes for services should be used when available. Nonspecific or not otherwise classified codes may be subject to additional documentation requirements and review.

CPT/HCPCS

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

References

1. Afkhami Ardekani M, Ghaffari H, Navaser M, et al. Effectiveness of rectal displacement devices in managing prostate motion: a systematic review. Strahlenther Onkol. 2021;197(2):97-115.

2. Aminsharifi A, Kotamarti S, Silver D, et al. Major complications and adverse events related to the injection of the SpaceOAR hydrogel system before radiotherapy for prostate cancer: review of the manufacturer and user facility device experience database. J Endourol. 2019;33(10):868-71.
3. Armstrong N, Bahl A, Pinkawa M, et al. SpaceOAR hydrogel spacer for reducing radiation toxicity during radiotherapy for prostate cancer. a systematic review. Urology. 2021;156:e74-e85.
4. Babayan RK, Steinberg ML, Miller LE. Re: Aminsharifi et al., Major complications and adverse events related to the injection of the SpaceOAR hydrogel system before radiotherapy for prostate cancer: review of the manufacturer and user facility device experience database (From: Aminsharifi A, Kotamarti S, Silver D, et al., J Endourol 2019;33:868-871; DOI: 10.1089/end.2019.0431). J Endourol. 2020;34(2):240-1.
5. Carvalho IT, Baccaglini W, Claros OR, et al. Genitourinary and gastrointestinal toxicity among patients with localized prostate cancer treated with conventional versus moderately hypofractionated radiation therapy: systematic review and meta-analysis. Acta Oncol. 2018;57(8):1003-10.
6. Chao Y, MacDougall D, de Nanassy A, et al. CADTH rapid response report: summary with critical appraisal. Hydrogel spacers for patients with prostate cancer: a review of clinical effectiveness and cost-effectiveness. 2019. [36 p.]. Available from: https://www.cadth.ca/hydrogel-spacers-patients-prostate-cancer-review-clinical-effectiveness-and-cost-effectiveness.
7. Eastham JA, Auffenberg GB, Barocas DA, et al. Clinically localized prostate cancer: AUA/ASTRO guideline. Part III: principles of radiation and future directions. J Urol. 2022;208(1):26-33.
8. Fransson P, Nilsson P, Gunnlaugsson A, et al. Ultra-hypofractionated versus conventionally fractionated radiotherapy for prostate cancer (HYPO-RT-PC): patient-reported quality-of-life outcomes of a randomised, controlled, non-inferiority, phase 3 trial. Lancet Oncol. 2021;22(2):235-45.
9. Fried DB, Dubose RS, Johnson K, et al. Dosimetry for organs at risk with and without use of perirectal hydrogel spacer in prostate cancer patients treated with SBRT. Int J Radiat Oncol Biol Phys. 2017;99 (2 Supplement):abstract 2559.
10. Hall WA, Tree AC, Dearnaley D, et al. Considering benefit and risk before routinely recommending SpaceOAR. Lancet Oncol. 2021;22(1):11-3.
11. Hamstra DA, Mariados N, Sylvester J, et al. Sexual quality of life following prostate intensity modulated radiation therapy (IMRT) with a rectal/prostate spacer: secondary analysis of a phase 3 trial. Pract Radiat Oncol. 2018;8(1):e7-e15.
12. Hamstra DA, Mariados N, Sylvester J, et al. Continued benefit to rectal separation for prostate radiation therapy: final results of a phase III trial. Int J Radiat Oncol Biol Phys. 2017;97(5):976-85.
13. Hoffman KE, Voong KR, Levy LB, et al. Randomized trial of hypofractionated, dose-escalated, intensity-modulated radiation therapy (IMRT) versus conventionally fractionated IMRT for localized prostate cancer. J Clin Oncol. 2018;36(29):2943-9.
14. Hrobjartsson A, Thomsen AS, Emanuelsson F, et al. Observer bias in randomized clinical trials with measurement scale outcomes: a systematic review of trials with both blinded and nonblinded assessors. CMAJ. 2013;185(4):E201-11.
15. Incrocci L, Wortel RC, Alemayehu WG, et al. Hypofractionated versus conventionally fractionated radiotherapy for patients with localised prostate cancer (HYPRO): final efficacy results from a randomised, multicentre, open-label, phase 3 trial. Lancet Oncol. 2016;17(8):1061-9.
16. Kahn J, Dahman B, McLaughlin C, et al. Rectal spacing, prostate coverage, and periprocedural outcomes after hydrogel spacer injection during low-dose-rate brachytherapy implantation. Brachytherapy. 2020;19(2):228-33.
17. King CR, Kamrava M, Wang PC, et al. In regard to Mariados et al. Int J Radiat Oncol Biol Phys. 2015;1(4):936-7.
18. Lawrie TA, Green JT, Beresford M, et al. Interventions to reduce acute and late adverse gastrointestinal effects of pelvic radiotherapy for primary pelvic cancers. Cochrane Database Syst Rev. 2018(1):article number CD012529.
19. Lewis SC, Warlow CP. How to spot bias and other potential problems in randomised controlled trials. J Neurol Neurosurg Psychiatry. 2004;75(2):181-7.
20. Lin YH, Loon W, Tacey M, et al. Impact of hydrogel and hyaluronic acid rectal spacer on rectal dosimetry and toxicity in low-dose-rate prostate brachytherapy: a multi-institutional analysis of patients' outcomes. J Contemp Brachytherapy. 2021;13(6):605-14.
21. Mariados N, Hamstra DA. In reply to King et al. Int J Radiat Oncol Biol Phys. 2015;1(4):937-9.
22. 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 Radiat Oncol Biol Phys. 2015;92(5):971-7.
23. Miller LE, Efstathiou JA, Bhattacharyya SK, et al. Association of the placement of a perirectal hydrogel spacer with the clinical outcomes of men receiving radiotherapy for prostate cancer: a systematic review and meta-analysis. JAMA Netw Open. 2020;3(6):e208221.
24. Morgan SC, Morton GC, Berlin A, et al. Current topics in radiotherapy for genitourinary cancers: consensus statements of the Genitourinary Radiation Oncologists of Canada. Can Urol Assoc J. 2020;14(11):E588-E93.
25. Nakai Y, Tanaka N, Asakawa I, et al. Efficacy of a hydrogel spacer for improving quality of life in patients with prostate cancer undergoing low-dose-rate brachytherapy alone or in combination with intensity-modulated radiotherapy: An observational study using propensity score matching. Prostate. 2024;84(12):1104-11. PMID: 38734992[5]

26. Nossiter J, Sujenthiran A, Cowling TE, et al. Patient-reported functional outcomes after hypofractionated or conventionally fractionated radiation for prostate cancer: a national cohort study in England. J Clin Oncol. 2020;38(7):744-52.
27. Ogita M, Yamashita H, Nozawa Y, et al. Phase II study of stereotactic body radiotherapy with hydrogel spacer for prostate cancer: acute toxicity and propensity score-matched comparison. Radiat Oncol. 2021;16(1):107.
28. Payne HA, Pinkawa M, Peedell C, et al. SpaceOAR hydrogel spacer injection prior to stereotactic body radiation therapy for men with localized prostate cancer: A systematic review. Medicine (Baltimore). 2021;100(49):e28111.
29. Quinn TJ, Daignault-Newton S, Bosch W, et al. Who benefits from a prostate rectal spacer? secondary analysis of a phase III trial. Pract Radiat Oncol. 2020;10(3):186-94.
30. Taggar AS, Charas T, Cohen GN, et al. Placement of an absorbable rectal hydrogel spacer in patients undergoing low-dose-rate brachytherapy with palladium-103. Brachytherapy. 2018;17(2):251-8.
31. Widmark A, Gunnlaugsson A, Beckman L, et al. Ultra-hypofractionated versus conventionally fractionated radiotherapy for prostate cancer: 5-year outcomes of the HYPO-RT-PC randomised, non-inferiority, phase 3 trial. Lancet. 2019;394(10196):385-95.
32. Yin Z, You J, Wang Y, et al. Moderate hypofractionated radiotherapy vs conventional fractionated radiotherapy in localized prostate cancer: a systemic review and meta-analysis from Phase III randomized trials. Onco Targets Ther. 2019;12:1259-68.
33. Zelefsky MJ, Pinitpatcharalert A, Kollmeier M, et al. Early tolerance and tumor control outcomes with high-dose ultrahypofractionated radiation therapy for prostate cancer. Eur Urol Oncol. 2019;3(6):748-55.

History

Status	Review Date	Effective Date	Action
Revised	07/17/2025	04/04/2026 except for LA Medicaid	Independent Multispecialty Physician Panel (IMPP) review. Added clarifying language to definitions and criteria sections.
Revised	07/16/2024	03/23/2025 except for LA Medicaid; 04/20/2025 for Premera	IMPP review. Revised indication for Hydrogel Spacer.
Reaffirmed	07/18/2023	Unchanged	IMPP review. Guidelines reaffirmed.
Reaffirmed	05/09/2022	Unchanged	IMPP review. Guidelines reaffirmed. Updated discussion and references.
Created	05/26/2021	11/07/2021	Original effective date. IMPP review. Moved hydrogel spacer content from the AIM Clinical Appropriateness Guidelines for Radiation Oncology. Added indication, discussion, and references.