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CLINICAL APPROPRIATENESS GUIDELINES

RADIATION ONCOLOGY

Appropriate Use Criteria: Perirectal Hydrogel Spacer for Prostate Radiotherapy

Proprietary

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Description and Application of the Guidelines

The AIM Clinical Appropriateness Guidelines (hereinafter “the AIM 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. As used by AIM, the Guidelines establish objective and evidence-based criteria for medical necessity determinations where possible. In the process, multiple functions are accomplished:

- 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 advocate for patient safety concerns
- To enhance the quality of health care
- To promote the most efficient and cost-effective use of services

The AIM guideline development process complies with applicable accreditation 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. Relevant citations are included in the References section attached to each Guideline. AIM reviews all of its Guidelines at least annually.

AIM makes its Guidelines publicly available on its website twenty-four hours a day, seven days a week. Copies of the AIM Clinical Appropriateness Guidelines are also available upon oral or written request. Although the Guidelines are publicly-available, AIM considers the Guidelines to be important, proprietary information of AIM, which cannot be sold, assigned, leased, licensed, reproduced or distributed without the written consent of AIM.

AIM 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 AIM 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. If requested by a health plan, AIM will review requests based on health plan medical policy/guidelines in lieu of the AIM Guidelines.

The Guidelines may also be used by the health plan or by AIM 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 should outweigh any potential harms that may result (net benefit).
- Current literature and/or standards of medical practice should support that the recommended intervention offers the greatest net benefit among competing alternatives.
- Based on the clinical evaluation, current literature, and standards of medical practice, there exists a reasonable likelihood that the intervention will change management and/or lead to an improved outcome for the patient.

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 supersede the requirements set forth above. During the peer-to-peer conversation, factors such as patient acuity and setting of service may also be taken into account.

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.

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. A pilot study authored by Song et al. documented the ability to increase the space between the prostate and rectum to an average of 7.5 mm. The additional space resulted in significant reductions in rectal dose across the range of 10 Gy to 75 Gy. No clinical outcomes were reported. Favorable early gastrointestinal (GI) and genitourinary (GU) toxicity profiles were reported in a phase II study by Uhl, but there was no control group for comparison.

External Beam Radiation Therapy

The only 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. Further studies are needed to define the role of hydrogel spacer placement, if any, in the setting of brachytherapy.

Systematic Reviews

A systematic review of the use of a hydrogel spacer to reduce toxicity during and after radiotherapy for prostate cancer was recently 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.

A recent Cochrane review of interventions to reduce acute and late adverse GI effects of pelvic radiotherapy 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."

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.

Disease 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

Intermediate risk of recurrence (ANY one characteristic)

- Stage T2b to T2c
- Gleason score of 7
- PSA 10-20 ng/mL

High risk of recurrence (ANY one characteristic)

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

Localized disease (BOTH 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)

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 low risk or intermediate risk prostate cancer using EITHER of the following techniques:

- Hypofractionated radiotherapy (28 fractions or fewer)
- Stereotactic Body Radiation Therapy

The use of an implanted hydrogel spacer is considered not medically necessary for all other indications.

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Codes

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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

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

History

<u>Status</u>	<u>Review Date</u>	<u>Effective Date</u>	<u>Action</u>
<u>Reaffirmed</u>	<u>05/09/2022</u>	<u>Unchanged</u>	<u>Independent Multispecialty Physician Panel (IMPP) review. Guidelines reaffirmed. Updated discussion and references.</u>
<u>Created</u>	<u>05/26/2021</u>	<u>11/07/2021</u>	<u>Original effective date. IMPP review. Moved hydrogel spacer content from the AIM Clinical Appropriateness Guidelines for Radiation Oncology. Added indication, discussion, and references.</u>