



# Geisinger Health Plan Policies and Procedure Manual

**Policy: MP320**

**Section: Medical Benefit Policy**

**Subject: Absorbable Hydrogel Spacer**

**Applicable line of business:**

<b>Commercial</b>	<b>x</b>	<b>Medicaid</b>	<b>x</b>
<b>Medicare</b>	<b>x</b>	<b>ACA</b>	<b>x</b>
<b>CHIP</b>	<b>x</b>		

**I. Policy: F**

**II. Purpose/Objective:**

To provide a policy of coverage regarding Absorbable Hydrogel Spacer

**III. Responsibility:**

- A. Medical Directors
- B. Medical Management

**IV. Required Definitions**

1. Attachment – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. Exhibit – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
3. Devised – the date the policy was implemented.
4. Revised – the date of every revision to the policy, including typographical and grammatical changes.
5. Reviewed – the date documenting the annual review if the policy has no revisions necessary.

**Commercial**

Geisinger Health Plan may refer collectively to health care coverage sponsors Geisinger Health Plan, Geisinger Quality Options, Inc., and Geisinger Indemnity Insurance Company, unless otherwise noted. Geisinger Health Plan is part of Geisinger, an integrated health care delivery and coverage organization.

**Medicare**

Geisinger Gold Medicare Advantage HMO, PPO, and HMO D-SNP plans are offered by Geisinger Health Plan/Geisinger Indemnity Insurance Company, health plans with a Medicare contract. Continued enrollment in Geisinger Gold depends on contract renewal. Geisinger Health Plan/Geisinger Indemnity Insurance Company are part of Geisinger, an integrated health care delivery and coverage organization.

**CHIP**

Geisinger Health Plan Kids (GHP Kids) is a Children's Health Insurance Program (CHIP) offered by Geisinger Health Plan in conjunction with the Pennsylvania Department of Human Services (DHS). Geisinger Health Plan is part of Geisinger, an integrated health care delivery and coverage organization.

**Medicaid**

Geisinger Health Plan Family (GHP Family) is a Medical Assistance (Medicaid) insurance program offered by Geisinger Health Plan in conjunction with the Pennsylvania Department of Human Services (DHS). Geisinger Health Plan is part of Geisinger, an integrated health care delivery and coverage organization.

## V. Additional Definitions

Medical Necessity or Medically Necessary means Covered Services rendered by a Health Care Provider that the Plan determines are:

- a. appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
- b. provided for the diagnosis, and the direct care and treatment of the Member's condition, illness disease or injury;
- c. in accordance with current standards of good medical treatment practiced by the general medical community.
- d. not primarily for the convenience of the Member, or the Member's Health Care Provider; and
- e. the most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

### Medicaid Business Segment

Medically Necessary — A service, item, procedure, or level of care that is necessary for the proper treatment or management of an illness, injury, or disability is one that:

- Will, or is reasonably expected to, prevent the onset of an illness, condition, injury or disability.
- Will, or is reasonably expected to, reduce or ameliorate the physical, mental or developmental effects of an illness, condition, injury or disability.
- Will assist the Member to achieve or maintain maximum functional capacity in performing daily activities, taking into account both the functional capacity of the Member and those functional capacities that are appropriate for Members of the same age

### DESCRIPTION:

The absorbable hydrogel spacer is designed to reduce unintentional rectal toxicity in men undergoing radiotherapy for treatment of prostate cancer. The hydrogel is administered using ultrasound guidance as a liquid that expands the space between the prostate and the rectal wall, where it solidifies into a soft, but firm, hydrogel within 10 seconds. The hydrogel remains in place for 3 months during prostate radiotherapy, after which it liquefies by hydrolysis, and is absorbed and cleared in the patient's urine.

### INDICATIONS:

Placement of an FDA-approved absorbable rectal hydrogel spacer (i.e. SpaceOAR) is considered medically necessary for the reduction of rectal and urinary toxicity in men with prostate cancer undergoing radiotherapy.

### EXCLUSIONS:

The use of absorbable hydrogel spacers outside of the indications listed in this policy are considered to be **unproven** and therefore, **NOT COVERED**. There is insufficient evidence in the peer-reviewed published medical literature to establish the effectiveness of this treatment for any other indication when compared to established tests or technologies.

### Medicaid Business Segment:

Any requests for services, that do not meet criteria set in the PARP, may be evaluated on a case by case basis

**Note: A complete description of the process by which a given technology or service is evaluated and determined to be experimental, investigational or unproven is outlined in MP 15 - Experimental Investigational or Unproven Services or Treatment.**

### CODING ASSOCIATED WITH: SpaceOAR Hydrogel Spacer

*The following codes are included below for informational purposes and may not be all inclusive. Inclusion of a procedure or device code(s) does not constitute or imply coverage nor does it imply or guarantee provider reimbursement. Coverage is determined by the member specific benefit plan document and any applicable laws regarding coverage of specific services. Please note that per Medicare coverage rules, only specific CPT/HCPCS Codes may be covered for the Medicare Business Segment. Please consult the CMS website at [www.cms.gov](http://www.cms.gov) or the local Medicare Administrative Carrier (MAC) for more information on Medicare coverage and coding requirements.*

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

**LINE OF BUSINESS:**

**Eligibility and contract specific benefits, limitations and/or exclusions will apply. Coverage statements found in the line of business specific benefit document will supersede this policy. For Medicare, applicable LCD's and NCD's will supercede this policy. For PA Medicaid Business segment, this policy applies as written.**

**REFERENCES:**

Geisinger Technology Assessment Committee, Triage Group, SpaceOAR System. May 2017

Whalley D, Hruby G, Alfieri F, Kneebone A, Eade T. SpaceOAR hydrogel in dose-escalated prostate cancer radiotherapy: rectal dosimetry and late toxicity. *Clin Oncol*. 2016;28(10):e148-e154.

Pinkawa M, Klotz J, Djukic V, et al. Learning curve in the application of a hydrogel spacer to protect the rectal wall during radiotherapy of localized prostate cancer. *Urology*. 2013;82(4):963-968.

Pieczonka CM, Mariados N, Sylvester JE, et al. Hydrogel spacer application technique, patient tolerance and impact on prostate intensity modulated radiation therapy: results from a prospective, multicenter, pivotal randomized controlled trial. *Urol Pract*. 2016;3(2):141-146.

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 maged intensity modulated radiation therapy. *Int J Radiat Oncol Biol Phys*. 2015;92(5):971-977.

Pinkawa M, Berneking V, König L, Frank D, Bretgeeld M, Eble MJ. Hydrogel injection reduces rectal toxicity after radiotherapy for localized prostate cancer. *Strahlenther Onkol*. 2016.

Wolf F, Gaisberger C, Ziegler I, et al. Comparison of two different rectal spacers in prostate cancer external beam radiotherapy in terms of rectal sparing and volume consistency. *Radiother Oncol*. 2015;116(2):221-225.

Pinkawa M, Berneking V, et al. Quality of Life After Radiation Therapy for Prostate Cancer With a Hydrogel Spacer: 5-Year Results. *Int J Radiat Oncol Biol Phys*. 2017 Oct 1;99(2):374-377

Jackson WC, Dess RT, et al. A multi-institutional phase 2 trial of prostate stereotactic body radiation therapy (SBRT) using continuous real-time evaluation of prostate motion with patient-reported quality of life. *Pract Radiat Oncol*. 2018 Jan - Feb;8(1):40-47

Tagger AS, Charas T, et al. Placement of an absorbable rectal hydrogel spacer in patients undergoing low-dose-rate brachytherapy with palladium-103. *Brachytherapy* 2017 Dec 11

Karsh L, Gross E, et al. Absorbable Hydrogel Spacer Use in Prostate Radiotherapy: A Comprehensive Review of Phase 3 Clinical Trial Published Data. *Urology*. 2017 Nov 23. pii: S0090-4295(17)31213

Berlin A, Di Tomasso A, et al. Use of hydrogel spacer for improved rectal dose-sparing in patients undergoing radical radiotherapy for localized prostate cancer: First Canadian experience. *Can Urol Assoc J*. 2017 Dec;11(12):373-375.

Wu SY, Boreta L, Wu A, et al. Improved rectal dosimetry with the use of SpaceOAR during high-dose-rate brachytherapy. *Brachytherapy*. 2017 Dec 1

Jones RT, Hassan Rezaeian N, Desai NB, et al. Dosimetric comparison of rectal-sparing capabilities of rectal balloon vs injectable spacer gel in stereotactic body radiation therapy for prostate cancer: lessons learned from prospective trials. *Med Dosim*. 2017. pii: S0958-3947(17)30067-5.

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  
This policy will be revised as necessary and reviewed no less than annually.

Hayes Inc. Health Technology Assessment. Absorbable Perirectal Spacer (SpaceOAR System; Augmenix Inc.) During Radiation Therapy For Prostate Cancer. Last update Apr.30, 2020

Te Velde BL, Westhuyzen J, Awad N, et al. Late toxicities of prostate cancer radiotherapy with and without hydrogel SpaceAOR insertion. *J Med Imaging Radiat Oncol*. 2019;63(6):836-841.

Aminsharifi A, Kotamarti S, Silver D, Schulman A. 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 (MAUDE) database. *J Endourol.* 2019;33(10):868-871.

Vaggers S, Rai BP, Chedgy ECP, de la Taille A, Somani BK. Polyethylene glycol-based hydrogel rectal spacers for prostate brachytherapy: A systematic review with a focus on technique. *World J Urol.* 2020 Aug 25

Seymour ZA, Hamstra DA, Daignault-Newton S, et al. Long-term follow-up after radiotherapy for prostate cancer with and without rectal hydrogel spacer: A pooled prospective evaluation of bowel-associated quality of life. *BJU Int.* 2020;126(3):367-372.

Miller LE, Efsthathiou JA, Bhattacharyya SK, Payne HA, Woodward E, Pinkawa M. 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

Dinh T-K T, Lee HJ Jr, Macomber MW, et al. Rectal hydrogel spacer improves late gastrointestinal toxicity compared to rectal balloon immobilization after proton beam radiation therapy for localized prostate cancer: A retrospective observational study. *Int J Radiat Oncol Biol Phys.* 2020;S0360-3016(20)30152-8.

Afkhami Ardekani M, Ghaffari H. Optimization of prostate brachytherapy techniques with polyethylene glycolbased hydrogel spacers: A systematic review. *Brachytherapy.* 2020;19(1):13-23.

Farjam R, Mahase SS, Chen SL, et al. Quantifying the impact of SpaceOAR hydrogel on inter-fractional rectal and bladder dose during 0.35 T MR-guided prostate adaptive radiotherapy. *J Appl Clin Med Phys.* 2021;22(9):49-58.

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

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

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

Teyateeti A, Grossman C, Kollmeier MA, et al. Influence of hydrogel spacer placement with prostate brachytherapy on rectal and urinary toxicity. *BJU Int.* 2022;129(3):337-344.

Song D, Dabkowski M, Costa P, et al. Prospective, randomized, controlled pivotal trial of biodegradable balloon rectal spacer for prostate radiation therapy. *Int J Radiat Oncol Biol Phys.* 2024 Jul 18

Kiriyama T, Fukui A, Ishikawa H, et al. Efficacy of hydrogel spacer compared with intensity-modulated radiotherapy for 3-dimensional conformal radiotherapy for prostate cancer. *Med Dosim.* 2025;50(3):203-208

Yates AH, Dempsey PJ, Power JW, et al. Rectal complications following SpaceOAR insertion after prior pelvic radiation. *BJR Case Rep.* 2025;11(2):uaaf013.

This policy will be revised as necessary and reviewed no less than annually.

**Devised:** 2/18

**Revised:** 2/26 (update Unproven language)

**Reviewed:** 2/19, 2/20, 2/21, 2/22, 2/23, 2/24, 2/25

**CMS UM Oversight Committee Approval:** 12/23, 5/24, 4/25, 4/26

Coverage for experimental or investigational treatments, services and procedures is specifically excluded under the member's certificate with Geisinger Health Plan. Unproven services outside of an approved clinical trial are also specifically excluded under the member's certificate with Geisinger Health Plan. This policy does not expand coverage to services or items specifically excluded from coverage in the member's certificate with Geisinger Health Plan. Additional information can be found in MP015 Experimental, Investigational or Unproven Services.

Prior authorization and/or pre-certification requirements for services or items may apply. Pre-certification lists may be found in the member's contract specific benefit document. Prior authorization requirements can be found at <https://www.geisinger.org/health-plan/providers/ghp-clinical-policies>

Please be advised that the use of the logos, service marks or names of Geisinger Health Plan, Geisinger Quality Options, Inc. and Geisinger Indemnity Insurance Company on a marketing, press releases or any communication piece regarding the contents of this medical policy is strictly prohibited without the prior written consent of Geisinger Health Plan. Additionally, the above medical policy does not confer any endorsement by Geisinger Health Plan, Geisinger Quality Options, Inc. and Geisinger Indemnity Insurance Company regarding the medical service, medical device or medical lab test described under this medical policy.