



PROVIDER POLICIES & PROCEDURES

IMPLANTATION OF A HYDROGEL SPACER DURING RADIOTHERAPY FOR PROSTATE CANCER

The primary purpose of this document is to assist providers enrolled in the Connecticut Medical Assistance Program (CMAP) with the information needed to support a medical necessity determination for the implantation of a hydrogel spacer during radiotherapy for prostate cancer. By clarifying the information needed for prior authorization of services, HUSKY Health hopes to facilitate timely review of requests so that individuals obtain the medically necessary care they need as quickly as possible.

A hydrogel spacer is a biodegradable, absorbable gel that may consist of polyethylene glycol (e.g., SpaceOAR) or hyaluronic acid (e.g., Barrigel). A hydrogel spacer temporarily positions the anterior rectal wall away from the prostate during radiotherapy for prostate cancer with the intent to reduce the radiation dose delivered to the anterior rectum. The absorbable spacer maintains space for the entire course of prostate radiotherapy treatment and is completely absorbed by the individual's body over time.

CLINICAL GUIDELINE

Coverage guidelines for the implantation of a hydrogel spacer during radiotherapy for prostate cancer are made in accordance with the DSS definition of Medical Necessity. The following criteria are guidelines only. Coverage determinations are based on an assessment of the individual and their unique clinical needs. If the guidelines conflict with the definition of Medical Necessity, the definition of Medical Necessity shall prevail. The guidelines are as follows:

Implantation of a hydrogel spacer is considered medically necessary for reducing rectal toxicity in men undergoing radiotherapy for prostate cancer.

Implantation of a hydrogel spacer is considered experimental and investigational for all other indications.

NOTE: EPSDT Special Provision

Early and Periodic Screening, Diagnosis, and Treatment (EPSDT) is a federal Medicaid requirement that requires the Connecticut Medical Assistance Program (CMAP) to cover services, products, or procedures for Medicaid enrollees under 21 years of age where the service or good is medically necessary health care to correct or ameliorate a defect, physical or mental illness, or a condition identified through a screening examination. The applicable definition of medical necessity is set forth in Conn. Gen. Stat. Section 17b-259b (2011) [ref. CMAP Provider Bulletin PB 2011-36].

PROCEDURE

Prior authorization of the implantation of a hydrogel spacer during radiotherapy for prostate cancer is required. Requests for coverage are reviewed in accordance with procedures in place for reviewing requests for surgical procedures. Coverage determinations are based upon a review of requested and/or

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submitted case-specific information.

The following information is needed to review requests for the implantation of a hydrogel spacer during radiotherapy for prostate cancer:

1. Fully completed authorization request via the on-line web portal; and
2. Documentation from the requesting physician supporting the medical necessity of the requested service.

EFFECTIVE DATE

This policy for the prior authorization of the implantation of a hydrogel spacer during radiotherapy for prostate cancer for individuals covered under the HUSKY Health Program is effective May, 1, 2022.

LIMITATIONS

Not Applicable

CODE:

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

DEFINITIONS

1. **HUSKY A:** Connecticut children and their parents or a relative caregiver; and pregnant women may qualify for HUSKY A (also known as Medicaid). Income limits apply.
2. **HUSKY B:** Uninsured children under the age of 19 in higher income households may be eligible for HUSKY B (also known as the Children's Health Insurance Program) depending on their family income level. Family cost-sharing may apply.
3. **HUSKY C:** Connecticut residents who are age 65 or older or residents who are ages 18-64 and who are blind, or have another disability, may qualify for Medicaid coverage under HUSKY C (this includes Medicaid for Employees with Disabilities (MED-Connect), if working). Income and asset limits apply.
4. **HUSKY D:** Connecticut residents who are ages 19-64 without dependent children and who: (1) do not qualify for HUSKY A; (2) do not receive Medicare; and (3) are not pregnant, may qualify for HUSKY D (also known as Medicaid for the Lowest-Income populations).
5. **HUSKY Health Program:** The HUSKY A, HUSKY B, HUSKY C, HUSKY D and HUSKY Limited Benefit programs, collectively.
6. **HUSKY Limited Benefit Program or HUSKY, LBP:** Connecticut's implementation of limited health insurance coverage under Medicaid for individuals with tuberculosis or for family planning purposes and such coverage is substantially less than the full Medicaid coverage.
7. **Medically Necessary or Medical Necessity:** (as defined in Connecticut General Statutes § 17b-259b) Those health services required to prevent, identify, diagnose, treat, rehabilitate or ameliorate an individual's medical condition, including mental illness, or its effects, in order to attain or maintain the individual's achievable health and independent functioning provided such services are: (1) Consistent with generally-accepted standards of medical practice that are defined as standards that are based on (A) credible scientific evidence published in peer-reviewed medical literature that is

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generally recognized by the relevant medical community, (B) recommendations of a physician-specialty society, (C) the views of physicians practicing in relevant clinical areas, and (D) any other relevant factors; (2) clinically appropriate in terms of type, frequency, timing, site, extent and duration and considered effective for the individual's illness, injury or disease; (3) not primarily for the convenience of the individual, the individual's health care provider or other health care providers; (4) not more costly than an alternative service or sequence of services at least as likely to produce equivalent therapeutic or diagnostic results as to the diagnosis or treatment of the individual's illness, injury or disease; and (5) based on an assessment of the individual and his or her medical condition.

8. **Prior Authorization:** A process for approving covered services prior to the delivery of the service or initiation of the plan of care based on a determination by CHNCT as to whether the requested service is medically necessary.

REFERENCES

- 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. doi:10.1016/j.urology.2021.05.013
- Babar M, Katz A, Ciatto M. Dosimetric and clinical outcomes of SpaceOAR in men undergoing external beam radiation therapy for localized prostate cancer: A systematic review. *J Med Imaging Radiat Oncol*. 2021;65(3):384-397. doi:10.1111/1754-9485.13179
- Chapet O, Udrescu C, Bin S, et al. Prostate hypofractionated radiotherapy (62Gy at 3.1Gy per fraction) with injection of hyaluronic acid: final results of the RPAH1 study. *Br J Radiol*. 2021;94(1124):20210242. doi:10.1259/bjr.20210242
- DiBiase SJ, Roach M. External beam radiation therapy for localized prostate cancer. In: *UpToDate*, Lee WR, Richie JP (Eds.). Wolters Kluwer. Updated May 30, 2025.
- European Association of Urology. Guidelines. Prostate Cancer. 2024. Available at: <https://www.uroweb.org/guidelines/prostate-cancer>.
- 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. doi:10.1002/acm2.13344
- 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. doi:10.1016/j.prro.2017.07.008
- 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):976-985. doi:10.1016/j.ijrobp.2016.12.024
- Hedrick SG, Fagundes M, Robison B, et al. A comparison between hydrogel spacer and endorectal balloon: An analysis of intrafraction prostate motion during proton therapy. *J Appl Clin Med Phys*. 2017;18(2):106-112. doi:10.1002/acm2.12051
- Hutchinson RC, Sundaram V, Folkert M, Lotan Y. Decision analysis model evaluating the cost of a temporary hydrogel rectal spacer before prostate radiation therapy to reduce the incidence of rectal complications. *Urol Oncol*. 2016;34(7):291.e19-291.e2.91E26. doi:10.1016/j.urolonc.2016.02.024
- Karsh LI, Gross ET, Pieczonka CM, et al. Absorbable Hydrogel Spacer Use in Prostate Radiotherapy: A Comprehensive Review of Phase 3 Clinical Trial Published Data. *Urology*. 2018;115:39-44. doi:10.1016/j.urology.2017.11.016

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- King RB, Osman SO, Fairmichael C, et al. Efficacy of a rectal spacer with prostate SABR-first UK experience. *Br J Radiol.* 2018;91(1083):20170672. doi:10.1259/bjr.20170672
- Latorzeff I, Bruguière E, Bogart E, et al. Use of a Biodegradable, Contrast-Filled Rectal Spacer Balloon in Intensity-Modulated Radiotherapy for Intermediate-Risk Prostate Cancer Patients: Dosimetric Gains in the BioPro-RCMI-1505 Study. *Front Oncol.* 2021;11:701998. Published 2021 Aug 26. doi:10.3389/fonc.2021.701998
- 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):605-614. doi:10.5114/jcb.2021.112110
- Mariados NF, Orio PF, Schiffman Z, et al. Hyaluronic Acid Spacer for Hypofractionated Prostate Radiation Therapy: A Randomized Clinical Trial. *JAMA Oncol.* 2023;9(4):511–518. doi:10.1001/jamaoncol.2022.7592
- 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):971-977. doi:10.1016/j.ijrobp.2015.04.030
- Miller LE, Efstathiou 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. doi:10.1001/jamanetworkopen.2020.8221
- National Comprehensive Cancer Network. Prostate Cancer (Version 2.2026). https://www.nccn.org/professionals/physician_gls/pdf/prostate.pdf.
- National Institute for Health and Care Excellence. Biodegradable spacer insertion to reduce rectal toxicity during radiotherapy for prostate cancer. Interventional Procedure Guidance 752. <https://www.nice.org.uk/guidance/ipg752>. Published February 7, 2023..
- Ozyigit G, Hurmuz P, Akinci D, et al. Hyaluronic acid spacer in focal prostate reirradiation: A single centre experience. *Cancer Radiother.* 2020;24(8):805-811. doi:10.1016/j.canrad.2020.03.009
- Pinkawa M, Berneking V, König L, Frank D, Bretgeld M, Eble MJ. Hydrogel injection reduces rectal toxicity after radiotherapy for localized prostate cancer. Hydrogelinjektion vermindert die rektale Toxizität nach Radiotherapie bei lokalisiertem Prostatakarzinom. *Strahlenther Onkol.* 2017;193(1):22-28. doi:10.1007/s00066-016-1040-6
- Pinkawa M, Berneking V, Schlentner M, Krenkel B, Eble MJ. Quality of Life After Radiation Therapy for Prostate Cancer With a Hydrogel Spacer: 5-Year Results. *Int J Radiat Oncol Biol Phys.* 2017;99(2):374-377. doi:10.1016/j.ijrobp.2017.05.035
- Song DY, Herfarth KK, Uhl M, et al. A multi-institutional clinical trial of rectal dose reduction via injected polyethylene-glycol hydrogel during intensity modulated radiation therapy for prostate cancer: Analysis of dosimetric outcomes. *Int J Radiat Oncol Biol Phys.* 2013;87(1):81-87.
- Te Velde BL, Westhuyzen J, Awad N, Wood M, Shakespeare TP. Late toxicities of prostate cancer radiotherapy with and without hydrogel SpaceAOR insertion [published correction appears in *J Med Imaging Radiat Oncol.* 2020 Apr;64(2):306]. *J Med Imaging Radiat Oncol.* 2019;63(6):836-841. doi:10.1111/1754-9485.12945
- 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. doi:10.1111/bju.15572

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- Uhl M, Herfarth K, Eble MJ, et al. Absorbable hydrogel spacer use in men undergoing prostate cancer radiotherapy: 12 month toxicity and proctoscopy results of a prospective multicenter phase II trial. *Radiat Oncol*. 2014;9:96.
- U.S. Food & Drug Administration. 510(k) Premarket Notification. Medical Device: Barrigel Injectable Gel. Available at: <https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm?ID=K220641>
- U.S. Food & Drug Administration. 510(k) Premarket Notification. Medical Device: SpaceOAR Vue Hydrogel. Available at: <https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm?ID=K182971>
- van Gysen K, Kneebone A, Alfieri F, Guo L, Eade T. Feasibility of and rectal dosimetry improvement with the use of SpaceOAR® hydrogel for dose-escalated prostate cancer radiotherapy. *J Med Imaging Radiat Oncol*. 2014;58(4):511-516. doi:10.1111/1754-9485.12152
- 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 (R Coll Radiol)*. 2016;28(10):e148-e154. doi:10.1016/j.clon.2016.05.005
- Wu SY, Boreta L, Wu A, et al. Improved rectal dosimetry with the use of SpaceOAR during high-dose-rate brachytherapy. *Brachytherapy*. 2018;17(2):259-264. doi:10.1016/j.brachy.2017.10.014

PUBLICATION HISTORY

Status	Date	Action Taken
Original Publication	March 2022	Approved at the February 9, 2022, CHNCT Medical Reviewer meeting. Approved by the CHNCT Clinical Quality Subcommittee on March 21, 2022. Approved by DSS on March 24, 2022
Update	March 2023	Updated Clinical Guideline section. PEG hydrogel is medically necessary for reducing rectal toxicity in men undergoing radiotherapy for prostate cancer. Change approved at the February 8, 2023, CHNCT Medical Reviewer meeting. Change approved by the CHNCT Clinical Quality Subcommittee on March 20, 2023. Approved by DSS on March 27, 2023.
Review	December 2023	Reviewed and approved without changes at the December 13, 2023, CHNCT Medical Reviewer meeting. Approved by the CHNCT Clinical Quality Subcommittee on December 18, 2023. Approved by DSS on January 03, 2024.
Reviewed	November 2024	Reviewed and approved without changes at the November 13, 2024 CHNCT Medical Reviewer meeting. Change approved by the CHNCT Clinical Quality Subcommittee on December 16, 2024. Approved by DSS on December 27, 2024.
Updated	November 2025	Title of policy updated to "Implantation of a Hydrogel Spacer During Radiotherapy for Prostate Cancer" to align with current literature and the scope of policy. Content throughout policy updated also, to reflect this change. References updated to reflect current literature and resources. Changes reviewed and approved at the November 12, 2025, CHNCT Medical Reviewer meeting. Changes approved by the CHNCT Clinical Quality Subcommittee on December 15, 2025. Approved by DSS on

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		December 26, 2025.
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