



PROVIDER POLICIES & PROCEDURES

IMPLANTATION OF POLYETHYLENE-GLYCOL (PEG) SPACING HYDROGEL (I.E. SPACEOAR SYSTEM)

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 implantation of polyethylene-glycol hydrogel (SpaceOAR System). 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.

Polyethylene glycol (PEG) hydrogel 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 patient's body over time.

CLINICAL GUIDELINE

Coverage guidelines for implantation of PEG hydrogel 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:

PEG hydrogel is **considered medically necessary** for individuals undergoing radiotherapy for prostate cancer.

PEG hydrogel is **considered experimental/investigational** and therefore not medically necessary for all other indications because the safety and or clinical efficacy cannot be established based on the available published peer-reviewed literature.

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 PEG hydrogel 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 submitted case-specific information.

Please note that authorization is based on medical necessity at the time the authorization is issued and is not a guarantee of payment. Payment is based on the individual having active coverage, benefits and policies in effect at the time of service.

To determine if a service or procedure requires prior authorization, CMAP Providers may refer to the *Benefit and Authorization Grids* summaries on www.ct.gov/husky by clicking on "For Providers" followed by "Benefit Grids". For a definitive list of benefits and service limitations, CMAP Providers may access the CMAP provider fee schedules and regulations at www.ctdssmap.com.

The following information is needed to review requests for PEG hydrogel:

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

EFFECTIVE DATE

This policy for the prior authorization for PEG hydrogel 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. **HUSKY Plus Physical Program (or HUSKY Plus Program):** A supplemental physical health program pursuant to Conn. Gen. Stat. § 17b-294, for medically eligible members of HUSKY B in Income Bands 1 and 2, whose intensive physical health needs cannot be accommodated within the HUSKY Plan, Part B.
8. **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

Please note that authorization is based on medical necessity at the time the authorization is issued and is not a guarantee of payment. Payment is based on the individual having active coverage, benefits and policies in effect at the time of service.

To determine if a service or procedure requires prior authorization, CMAP Providers may refer to the *Benefit and Authorization Grids* summaries on www.ct.gov/husky by clicking on “For Providers” followed by “Benefit Grids”. For a definitive list of benefits and service limitations, CMAP Providers may access the CMAP provider fee schedules and regulations at www.ctdssmap.com.

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 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.

9. **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
- 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.ppro.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
- 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
- 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

Please note that authorization is based on medical necessity at the time the authorization is issued and is not a guarantee of payment. Payment is based on the individual having active coverage, benefits and policies in effect at the time of service.

To determine if a service or procedure requires prior authorization, CMAP Providers may refer to the *Benefit and Authorization Grids* summaries on www.ct.gov/husky by clicking on "For Providers" followed by "Benefit Grids". For a definitive list of benefits and service limitations, CMAP Providers may access the CMAP provider fee schedules and regulations at www.ctdssmap.com.

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

- National Comprehensive Cancer Network. Prostate cancer (Version 3.2022). https://www.nccn.org/professionals/physician_gls/pdf/prostate.pdf. Accessed February 7, 2022.
- National Institute for Health and Care Excellence. Biodegradable spacer insertion to reduce rectal toxicity during radiotherapy for prostate cancer. *Interventional Procedure Guidance 590*. <https://www.nice.org.uk/guidance/ipg590>. Published August, 2017. Accessed February 7, 2022.
- 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, Schlenter 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
- 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.
- 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 |

Please note that authorization is based on medical necessity at the time the authorization is issued and is not a guarantee of payment. Payment is based on the individual having active coverage, benefits and policies in effect at the time of service.

To determine if a service or procedure requires prior authorization, CMAP Providers may refer to the *Benefit and Authorization Grids* summaries on www.ct.gov/husky by clicking on "For Providers" followed by "Benefit Grids". For a definitive list of benefits and service limitations, CMAP Providers may access the CMAP provider fee schedules and regulations at www.ctdssmap.com.