



Prostate Cancer Treatment

LOB(s): <input checked="" type="checkbox"/> Commercial <input checked="" type="checkbox"/> Medicare <input checked="" type="checkbox"/> Medicaid	State(s): <input checked="" type="checkbox"/> Idaho <input checked="" type="checkbox"/> Montana <input checked="" type="checkbox"/> Oregon <input checked="" type="checkbox"/> Washington <input type="checkbox"/> Other: <input checked="" type="checkbox"/> Oregon <input type="checkbox"/> Washington
--	---

Enterprise Policy

PacificSource is committed to assessing and applying current regulatory standards, widely-used treatment guidelines, and evidenced-based clinical literature when developing clinical criteria for coverage determination. Each policy contains a list of sources (references) that serves as the summary of evidence used in the development and adoption of the criteria. The evidence was considered to ensure the criteria provide clinical benefits that promote patient safety and/or access to appropriate care. Each clinical policy is reviewed, updated as needed, and readopted, at least annually, to reflect changes in regulation, new evidence, and advancements in healthcare.

Clinical Guidelines are written when necessary to provide guidance to providers and members in order to outline and clarify coverage criteria in accordance with the terms of the Member's policy. This Clinical Guideline only applies to PacificSource Health Plans, PacificSource Community Health Plans, and PacificSource Community Solutions in Idaho, Montana, Oregon, and Washington. Because of the changing nature of medicine, this list is subject to revision and update without notice. This document is designed for informational purposes only and is not an authorization or contract. Coverage determinations are made on a case-by-case basis and subject to the terms, conditions, limitations, and exclusions of the Member's policy. Member policies differ in benefits and to the extent a conflict exists between the Clinical Guideline and the Member's policy, the Member's policy language shall control. Clinical Guidelines do not constitute medical advice nor guarantee coverage.

Background

High-intensity focused ultrasound (HIFU) is a non-invasive therapeutic technique that uses non-ionizing ultrasonic waves to ablate cancer tissue in a focused area. Treatment of recurrent prostate cancer depends on factors such as the primary treatment method, extent of the cancer, and site of recurrence.

Perirectal spacers may be utilized during treatment of prostate cancer. These products increase the distance between the rectum and the prostate to reduce radiation of the rectum from the external beam radiation therapy (EBRT) field and brachytherapy (internal radiation implant).

Proton Beam Therapy is a type of external radiation treatment in which positively charged subatomic particles (protons) are precisely targeted to a specific tissue mass using a sophisticated stereotactic planning and delivery system. Compared with conventional radiation, Proton Beam Therapy may deliver a higher radiation dose to the target tissue while minimizing damage to surrounding healthy tissue.

The goal of this implantation is to separate the rectum from the prostate to decrease rectal exposure during radiation treatment for prostate cancer.

Criteria

Commercial

Prior authorization is required

I. High-Intensity Focused Ultrasound (HIFU)

- A. PacificSource considers High-Intensity Focused Ultrasound (HIFU) to be medically necessary for recurrent prostate cancer when the **ALL** of the following criteria is met:
1. Radiation therapy has been completed
 2. Positive digital rectal exam **OR** Prostate-Specific Antigen (PSA) has been confirmed to be increasing
 3. Patient is a candidate for local therapy as evidenced by the following criteria
 - a. Original clinical stage T1-T2, NX or N0 (see Definitions)
 - b. PSA now less than 10 ng/mL
 4. Biopsy is positive or suspicious of recurrence of prostate cancer
 5. Absence of metastatic disease

II. Radiation for Prostate Therapy

- A. PacificSource follows MCG A-0694 (AC) for Stereotactic Body Radiotherapy and MCG: A-0389 (AC) for Proton Beam Therapy radiation for Prostate Cancer
- B. PacificSource (Oregon) covers members diagnosed with prostate cancer for proton beam therapy per Oregon Senate Bill 463, ORS 743A.130

NOTE: Coverable diagnosis:

1. C61 Malignant neoplasm of prostate
2. D07.5 Carcinoma in situ of prostate
3. D40.0 Neoplasm of uncertain behavior of prostate
4. Z85.46 Personal history of malignant neoplasm of prostate

III. Hydrogel Perirectal Spacers

- A. PacificSource considers the use of hydrogel perirectal spacers (e.g., SpaceOAR™) medically necessary for reducing rectal toxicity when documentation supports **ALL** of the following criteria
1. Diagnosis of clinically localized prostate cancer (without posterior extraprostatic extension)
 2. Stereotactic body radiotherapy is planned
 3. Tumor has not invaded the rectum

Medicaid

PacificSource Community Solutions follows Guideline Note 173 of the OHP Prioritized List of Health Services and considers High-intensity Focused Ultrasound (HIFU) for Prostate Cancer Recurrence insufficient due to lack of evidence of effectiveness and Absorbable Perirectal Spacers for use during prostate cancer radiation therapy an unproven treatment.

Medicare

PacificSource Medicare follows CMS guidelines and criteria. In the absence of CMS guidelines and criteria, PacificSource Medicare will follow internal policy for determination of coverage and medical necessity.

Experimental/Investigational/Unproven

PacificSource considers High-intensity focused ultrasound (HIFU), including magnetic resonance (MRI)-guided focused ultrasound, to be experimental, investigational, or unproven for any other indication, including as an initial treatment for localized prostate cancer

PacificSource considers the use of hydrogel perirectal spacers experimental, investigational, or unproven for all other indications

Coding Information

The following list of codes are for informational purposes only and may not be all-inclusive. Deleted codes and codes which are not effective at the time the service is rendered may not be eligible for reimbursement.

- 55874 Transperineal placement of biodegradable material, periprostatic, single or multiple injections, including image guidance, when performed
- 55880 Ablation of malignant prostate tissue, transrectal, with high intensity-focused ultrasound (HIFU), including ultrasound guidance
- 55899 Unlisted procedure, male genital system (when specified as image-guided focused ultrasound ablation of prostate tissue for non-oncologic indications, such as benign prostatic hyperplasia)
- 77520 Proton treatment delivery; simple, without compensation
- 77522 Proton treatment delivery; simple, with compensation
- 77523 Proton treatment delivery; intermediate
- 77525 Proton treatment delivery; complex
- C9734 Focused ultrasound ablation/therapeutic intervention, other than uterine leiomyomata, with magnetic resonance (MR) guidance

CPT® codes, descriptions and materials are copyrighted by the American Medical Association (AMA).

HCPCS® codes, descriptions and materials are copyrighted by Centers for Medicare and Medicaid Services (CMS).

Definitions

Prostate-Specific Antigen (PSA) – laboratory test that measures the amount of protein made by the prostate gland found in the blood.

Prostate-Specific Antigen (PSA) nadir – the absolute lowest level the PSA drops after treatment, which is a value of 2 ng/ml greater than their lowest value.

Prostate Cancer Staging - method of evaluating cancer by detailing size of tumor, if lymph nodes are affected, and if the tumor has metastasized as detailed below:

Stage I - Prostate cancer cannot be felt by digital rectal examination, causes no symptoms, and is only in the prostate, usually found incidentally in a prostatectomy specimen when surgery is done for benign prostatic hyperplasia

Stage II - Cancer confined to the prostate gland found by needle biopsy done for an elevated prostate-specific antigen (PSA) level or after rectal examination reveals a mass in the prostate

Stage III - Cancer cells have spread outside the capsule of the prostate to tissues around the prostate (e.g., seminal vesicles)

Stage IV - Cancer cells have metastasized to lymph nodes or to organs and tissues (e.g., the bone, liver, or lungs)

TNM System - evaluation method developed to stage prostate cancer that separates tumor (T), lymph nodes (N) and metastases (M) as shown below:

Tumor (T) Staging:

T1 - The tumor is too small to be seen on scans or felt during examination of the prostate

T2 - The tumor is completely inside the prostate gland

T3 - The tumor has broken through the capsule of the prostate gland

T4 - The tumor has spread into other body organs

Lymph Node (N) Staging:

NX - Cancer in nearby lymph nodes cannot be measured, unable to be assessed

N0 - No cancer cells found in any lymph nodes

N1 - One positive lymph node smaller than 2 cm across

N2 - More than 1 positive lymph node; or one that is between 2 cm and 5 cm across

N3 - Any positive lymph node that is bigger than 5 cm across

Metastases (M) Staging:

M0 - No cancer spread outside the pelvis

M1 - Cancer has spread outside the pelvis

References

Crouzet, S., Blana, A., Murat, F. J., Pasticier, G., Brown, S., Conti, G. N., Ganzer, R., Chapet, O., Gelet, A., Chaussy, C. G., Robertson, C. N., Thuroff, S., & Ward, J. F. (2017). Salvage high-intensity focused ultrasound (HIFU) for locally recurrent prostate cancer after failed radiation therapy: Multi-institutional analysis of 418 patients. *BJU international*, 119(6).

<https://www.ncbi.nlm.nih.gov/pubmed/28063191>

Golan, R., Bernstein, A. N., McClure, T. D., Sedrakyan, A., Patel, N. A., Parekh, D. J., Marks, L. S., & Hu, J. C. (2017). Partial Gland Treatment of Prostate Cancer Using High-Intensity Focused Ultrasound in the Primary and Salvage Settings: A Systematic Review. *The Journal of urology*, 198(5), 1000–1009. <https://www.ncbi.nlm.nih.gov/pubmed?term=28433640>

Hamstra, D. A., Mariados, N., Sylvester, J., Shah, D., Karsh, L., Hudes, R., Beyer, D., Kurtzman, S., Bogart, J., Hsi, R. A., Kos, M., Ellis, R., Logsdon, M., Zimberg, S., Forsythe, K., Zhang, H., Soffen, E.,

Francke, P., Mantz, C., Rossi, P., ... Michalski, J. (2017). Continued Benefit to Rectal Separation for Prostate Radiation Therapy: Final Results of a Phase III Trial. *International journal of radiation oncology, biology, physics*, 97(5), 976–985. <https://doi.org/10.1016/j.ijrobp.2016.12.024>

Hayes Knowledge Center. (2021, September 27). Health Technology Assessment. Absorbable Perirectal Spacer (SpaceOAR System; Boston Scientific) During Radiation Therapy for Prostate Cancer. <https://evidence.hayesinc.com/report/htb.spaceoar3407>

Hayes Knowledge Center. (May 6, 2021). Health Technology Assessment: High Intensity Focused Ultrasound for Salvage therapy of Recurrent Prostate Cancer. <https://evidence.hayesinc.com/report/dir.hifurecurrent3948>

Hayes Knowledge Center. (November 22, 2022). Health Technology Assessment: Ultrasound-Guided High-Intensity focused Ultrasound for Primary Treatment of Localized Prostate Cancer. <https://evidence.hayesinc.com/report/dir.hifu747>

Hayes Knowledge Center: Proton Beam Therapy for Prostate Cancer. Hayes Knowledge Center | symplr. (2023, April 11). <https://evidence.hayesinc.com/report/dir.prot0003>

Jones, T. A., Chin, J., Mcleod, D., Barkin, J., Pantuck, A., & Marks, L. S. (2018). High Intensity Focused Ultrasound for Radiorecurrent Prostate Cancer: A North American Clinical Trial. *The Journal of urology*, 199(1), 133–139. <https://www.ncbi.nlm.nih.gov/pubmed/28652121>

Karsh, L. I., Gross, E. T., Pieczonka, C. M., Aliotta, P. J., Skomra, C. J., Ponsky, L. E., Nieh, P. T., Han, M., Hamstra, D. A., & Shore, N. D. (2018). Absorbable Hydrogel Spacer Use in Prostate Radiotherapy: A Comprehensive Review of Phase 3 Clinical Trial Published Data. *Urology*, 115, 39–44. <https://doi.org/10.1016/j.urology.2017.11.016> National Institute for Health and Care Excellence (NICE). (2017, August 23). Biodegradable spacer insertion to reduce rectal toxicity during radiotherapy for prostate cancer. Available at: <https://www.nice.org.uk/guidance/ipg590>

MCG 27th edition High Intensity focused Ultrasound (HIFU), Prostate, ACG: A-0271, 2022, MCG Health, LLC <https://careweb.careguidelines.com/ed26/index.html>

National Comprehensive Cancer Network (NCCN) Prostate Cancer Clinical Practice Guidelines in Oncology, Version 2.2019 Prostate Cancer. https://www.nccn.org/professionals/physician_gls/pdf/prostate.pdf

Paetkau, O., Gagne, I. M., Pai, H. H., Lam, J., Goulart, J., & Alexander, A. (2019). Maximizing rectal dose sparing with hydrogel: A retrospective planning study. *Journal of applied clinical medical physics*, 20(4), 91–98. doi.org/10.1002/acm2.12566

Radiation therapy for prostate cancer. American Cancer Society. (2023, February 13). <https://www.cancer.org/cancer/types/prostate-cancer/treating/radiation-therapy.html>

Te Velde, B. L., Westhuyzen, J., Awad, N., Wood, M., & Shakespeare, T. P. (2019). Late toxicities of prostate cancer radiotherapy with and without hydrogel SpaceAOR insertion. *Journal of medical imaging and radiation oncology*, 63(6), 836–841. <https://doi.org/10.1111/1754-9485.12945>

UpToDate: Cryotherapy and other ablative techniques for the initial treatment of prostate cancer. Wolters Kluwer, UpToDate, Inc. <https://www.uptodate.com/contents/cryotherapy-and-other-ablative-techniques-for-the-initial-treatment-of-prostate-cancer>

Appendix

Policy Number:

Effective: 12/9/2021

Next review: 11/1/2024

Policy type: Enterprise

Author(s): Eric Lowery

Depts: Health Services

Applicable regulation(s): Guideline Note 173, Oregon Administrative Rules (OAR) 410-120-1200 and 410-141-3820 to 3830, OR SB 463, ORS 743A.130.

Commercial Ops: 2/2024

Government Ops: 2/2024