

Radiation Oncology

Akido Labs | MCG Care Guidelines, 30th Edition

1. MCG Criteria Used

Clinical Criteria: MCG Care Guidelines, 30th Edition

- Brachytherapy: Ambulatory Care (MCG ORG: A-0270 AC, 30th Edition)

Applicable CPT / HCPCS Codes:

CPT / HCPCS Code	Description
77750-77761	Brachytherapy: intracavitary application, simple, intermediate, and complex (LDR and HDR)
77770-77778	Remote afterloading high dose rate brachytherapy: 1 channel through multiple channels
77261-77295	Radiation oncology treatment planning: simulation, dosimetry, and dose plan preparation for brachytherapy
77300-77328	Basic radiation dosimetry calculations and isodose planning for brachytherapy
77332-77340	Radiation treatment aids: preparation and construction of radiation therapy devices
77789	Surface application of low dose rate radionuclide source
99213-99215	Evaluation and management: radiation oncology consultation and treatment follow-up visits

2. Statement of Rationale

Akido Labs uses the criteria in MCG Care Guidelines (30th Edition) to supplement the general Medicare criteria regarding radiation oncology services, including ambulatory care determinations for brachytherapy, where Medicare coverage criteria are not fully established or require additional clinical specificity regarding cancer-site-specific clinical indications and patient selection criteria for this specialized radiation delivery modality. MCG criteria are used to ensure consistency in reviewing the conditions to be met for coverage of brachytherapy and to determine when such services are medically necessary. Brachytherapy delivers radiation directly to tumor tissue through intracavitary or interstitial radioactive source placement, offering highly targeted local radiation delivery that substantially reduces dose to surrounding normal structures compared with external beam radiation alone. Radiation oncology services represent a complex, high-cost category of cancer care in the Medicare Advantage population, where cancer incidence is disproportionately elevated. Brachytherapy is the standard of care or a required component of standard treatment for multiple common cancer types in this population including cervical, endometrial, prostate, and breast cancer. Absent consistent, evidence-based criteria, there is risk of both inappropriate denial of clinically indicated brachytherapy and authorization without adequate documentation of cancer type, stage, and patient-specific selection criteria.

Potential Clinical Harms:

Inappropriate denial: Denial of brachytherapy for a patient with locally advanced cervical cancer (standard of care per NCCN and American Brachytherapy Society guidelines), endometrial cancer with high-risk pathology or positive vaginal margins, or low-risk prostate cancer eligible for LDR brachytherapy monotherapy (per NCCN Category 1 recommendation) could result in suboptimal cancer treatment, inferior local control, higher recurrence rates, and reduced cancer-specific survival. For locally advanced cervical cancer, chemoradiation plus intracavitary brachytherapy achieves local control rates of 80% to 90% for stage IB-IIA disease; substitution with external beam radiation alone yields substantially inferior outcomes. Denial of brachytherapy for appropriate candidates constitutes a departure from the established standard of care with direct consequences for cancer outcomes.

Inappropriate approval without documentation: Authorization of brachytherapy without documentation of appropriate cancer type, histology, stage, and patient fitness for the specific brachytherapy approach (intracavitary, interstitial, LDR, HDR) could result in procedural complications including urologic or gastrointestinal toxicity, infection, or implant-related complications in patients who are not appropriate candidates or for whom external beam radiation alone is the more appropriate treatment modality.

Clinical Benefits:

Comprehensive cancer-site-specific evidence-based indications: MCG A-0270 criteria provide evidence-based brachytherapy indications across multiple cancer sites including gynecologic cancers (cervical, endometrial, vaginal), prostate cancer, breast cancer, and other malignancies, aligned with NCCN Clinical Practice Guidelines and American Brachytherapy Society (ABS) guidelines. The guideline is supported by 80 published peer-reviewed articles, 21 specialty society guidelines, and 3 Cochrane systematic reviews. This comprehensive evidence base directly supports identification of patients for whom brachytherapy is the appropriate treatment versus those for whom alternative radiation modalities are preferred.

Normal tissue sparing and toxicity reduction: Brachytherapy delivers radiation with rapid dose falloff, substantially reducing radiation dose to surrounding normal structures (bladder, rectum, small bowel, urethra) compared with external beam radiation alone. Evidence from GEC-ESTRO prospective trials demonstrates that image-guided adaptive brachytherapy for locally advanced cervical cancer achieves equivalent or superior local control to historical external beam series with significantly lower rates of late bladder and rectal toxicity, directly addressing the harm of inadequate cancer treatment associated with denial of brachytherapy.

Prostate cancer outcome equivalence: For low-risk and favorable intermediate-risk prostate cancer, evidence from multiple prospective cohort studies and randomized trials demonstrates that LDR brachytherapy monotherapy achieves 10-year biochemical relapse-free survival rates of 85% to 95%, equivalent to radical prostatectomy and external beam radiation, with a favorable toxicity profile. NCCN Category 1 recommendations support LDR brachytherapy as an appropriate monotherapy option for low-risk and selected intermediate-risk prostate cancer, supporting MCG criteria for this indication.

Reduction of unwarranted variation: Standardized MCG criteria reduce care disparities by applying consistent evidence-based cancer-site-specific brachytherapy indications across diverse patient populations, facilities, and geographic regions, supporting equitable access to this specialized but important radiation modality. The clinical benefits of using MCG Care Guidelines are highly likely to outweigh any clinical harms, including delayed or decreased access to services. The criteria incorporate validated NCCN and ABS guideline indications drawn from current radiation oncology specialty society standards and are unlikely to lead to inappropriate denials for patients with documented appropriate cancer indications. Use of these criteria ensures patients receive the most clinically appropriate radiation modality and decreases inappropriate denials by applying a consistent, objective, evidence-based set of review criteria across the Medicare Advantage population.

3. Explanation of Supplementation

Basis for Use: Original Medicare clinical criteria are not fully established and require supplementation to ensure consistent medical necessity determinations for brachytherapy. While Medicare covers radiation oncology services generally under the reasonable and necessary standard and certain brachytherapy services are addressed in NCDs and LCDs, specific brachytherapy indications by cancer type and stage, patient fitness criteria, and clinical decision-making for brachytherapy versus external beam radiation require additional specificity beyond existing Medicare coverage frameworks.

Applicable Medicare References: Social Security Act Section 1862(a)(1): Reasonable and necessary standard Medicare Benefit Policy Manual, Chapter 1: Inpatient Hospital Services Covered Under Part A (CMS IOM Publication 100-02) Medicare Benefit Policy Manual, Chapter 6: Hospital Services Covered Under Part B (CMS IOM Publication 100-02) Medicare Benefit Policy Manual, Chapter 15: Covered Medical and Other Health Services (CMS IOM Publication 100-02) Medicare Program Integrity Manual, Chapter 6, Section 6.5: Medical Review of Inpatient Hospital Claims for Part A Payment (CMS IOM Publication 100-08) Code of Federal Regulations: 42 CFR 412.3; 42 CFR 419.22; 42 CFR 422.101 Conditions of Participation: Discharge Planning (42 CFR 482.43) No specific NCD or LCD fully establishes clinical thresholds for all of these services. Original Medicare criteria are not fully established, requiring supplementation. Medicare Coverage Database: <https://www.cms.gov/medicare-coverage-database/search.aspx> Within the above statutes and regulations, coverage criteria for brachytherapy are not fully established for all clinical indications, and the use of MCG Care Guidelines is necessary to provide additional clinical specificity. Specifically, MCG criteria assist in determining: Appropriate clinical indication for brachytherapy based on cancer type, histology, stage, and NCCN or ABS guideline recommendation for the specific brachytherapy approach; Patient fitness and anatomic eligibility for specific brachytherapy approaches (intracavitary, interstitial, low-dose-rate, high-dose-rate) based on tumor geometry, prior radiation history, and comorbidity assessment; Appropriateness of brachytherapy as monotherapy versus as a boost following external beam radiation, based on cancer type, stage, and evidence-based treatment paradigm; Documentation of radiation oncology specialist evaluation and, where appropriate, multidisciplinary tumor board discussion supporting brachytherapy selection as the appropriate treatment modality. The use of MCG Care Guidelines ensures consistency in reviewing the conditions to be met for coverage of brachytherapy. Use of these criteria to supplement the coverage criteria noted above provides clinical benefits by helping ensure brachytherapy is not incorrectly denied when medically appropriate, nor incorrectly approved when not reasonable and necessary. The clinical benefits of using these criteria are highly likely to outweigh any clinical harms, including from inappropriate denials, because the criteria are unlikely to lead to inappropriate denials and will decrease unwarranted variation through a consistent set of evidence-based review criteria.

4. Summary of Clinical Evidence

Note: The following evidence summary is derived directly from MCG Care Guidelines, 30th Edition (AC guideline A-0270). The reference list below is drawn from the MCG A-0270 guideline. Background Brachytherapy is a form of radiation therapy that involves the implantation of radioactive seeds or sources in or near an existing tumor to maximize delivery of radiation to cancerous cells while minimizing exposure and potential damage to adjacent normal structures. High-dose-rate (HDR) brachytherapy consists of the placement of thin catheters into the tumor; a radioactive pellet (e.g., iridium) is sequentially introduced into each catheter for a predetermined amount of time to deliver radiation. Low-dose-rate (LDR) brachytherapy involves permanent or temporary implantation of radioactive seeds (e.g., iodine-125, palladium-103) that deliver

radiation over days to weeks. Brachytherapy is used for cancers of the cervix, endometrium, vagina, prostate, breast, and other sites. The MCG A-0270 Brachytherapy guideline encompasses an evidence base of 80 published peer-reviewed articles, 21 specialty society or other evidence-based guidelines, and 3 Cochrane systematic reviews. Evidence Summary The MCG Brachytherapy guideline (30th Edition, ORG: A-0270 AC) is supported by 80 published peer-reviewed articles, 21 specialty society or other evidence-based guidelines, and 3 Cochrane systematic reviews. Key evidence by cancer site includes: Breast cancer: A systematic review identified 3 randomized trials (5,574 patients) comparing brachytherapy with whole breast radiotherapy after breast-conserving surgery for early-stage breast cancer and found no statistically significant difference in local recurrence between partial breast irradiation using brachytherapy and whole breast radiotherapy in appropriately selected patients. Cervical cancer: Evidence from GEC-ESTRO prospective observational studies demonstrates that image-guided adaptive brachytherapy for locally advanced cervical cancer achieves local control rates of 90% to 95% for stage IB-IIIB disease with significantly lower rates of late Grade 3 to 4 bladder and rectal toxicity compared with historical external beam series, establishing brachytherapy as a required component of standard-of-care treatment per NCCN Category 1 recommendation. Prostate cancer: Evidence from multiple prospective cohort studies demonstrates LDR brachytherapy monotherapy achieves 10-year biochemical relapse-free survival rates of 85% to 95% for low-risk prostate cancer, equivalent to radical prostatectomy and external beam radiation. A randomized trial of dose-escalated external beam radiotherapy with and without LDR brachytherapy boost demonstrated significantly improved 5-year freedom from biochemical failure with combined therapy in intermediate- and high-risk prostate cancer. Endometrial cancer: Evidence from randomized controlled trials including PORTEC-2 demonstrates that vaginal brachytherapy alone achieves equivalent local control to external beam pelvic radiotherapy for low- and intermediate-risk endometrial cancer with lower rates of gastrointestinal toxicity, supporting brachytherapy as the preferred adjuvant radiation modality for appropriately staged endometrial cancer. NCCN Clinical Practice Guidelines and American Brachytherapy Society guidelines, incorporated into MCG A-0270, provide evidence-based cancer-site-specific brachytherapy indications representing the current standard of care across gynecologic, prostate, and breast cancer applications. Rationale (from MCG) Use of this MCG care guideline helps the clinician identify specific complex factors of a patient's condition that may need a specific procedure, diagnostic test, or specialist consultation. It provides evidence-based clinical criteria to ensure timely, appropriate care and limit unnecessary differences in treatment, thereby promoting equal access and quality of care for similar patients, regardless of location, facility, or clinician. These guidelines supplement but do not replace, modify, or supersede existing Medicare regulations or applicable National Coverage Determinations (NCDs) or Local Coverage Determinations (LCDs).

Related CMS Coverage Guidance (as cited in MCG 30th Edition): Code of Federal Regulations (CFR): 42 CFR 412.3; 42 CFR 419.22; 42 CFR 422.101 CMS IOM Publication 100-02, Medicare Benefit Policy Manual: Chapter 1 (Inpatient Hospital Services); Chapter 6 (Hospital Services Under Part B); Chapter 15 (Covered Medical and Other Health Services) CMS IOM Publication 100-08, Medicare Program Integrity Manual, Chapter 6, Section 6.5 Medicare Coverage Database: <https://www.cms.gov/medicare-coverage-database/search.aspx> References with Citation Summary -- Brachytherapy (MCG ORG: A-0270 AC, 30th Edition) ACR-ABS-ASTRO Practice Parameter for the Performance of Radionuclide-Based High-Dose-Rate Brachytherapy. [Internet] American College of Radiology and the American Brachytherapy Society. 2020 Accessed at: <https://www.acr.org/>. [created 1996; accessed 2025 May 30] Viswanathan AN, Thomadsen B, American Brachytherapy Society Cervical Cancer Recommendations Committee, American Brachytherapy Society. American Brachytherapy Society consensus guidelines for locally advanced carcinoma of the cervix. Part I: general principles. Brachytherapy 2012 Jan-Feb;11(1):33-46. DOI: 10.1016/j.brachy.2011.07.003. (Reaffirmed 2025 Jun) Lee CD. Recent developments and best practice in brachytherapy treatment planning. British Journal of Radiology 2014;87(1041):20140146. DOI: 10.1016/j.bjr.20140146. Zamboglou N, et al. High-dose-rate interstitial brachytherapy as monotherapy for clinically localized prostate cancer: treatment evolution and mature results. International Journal of Radiation Oncology, Biology and Physics 2013;85(3):672-678. DOI: 10.1016/j.ijrobp.2012.07.004. Martinez AA, Demanes J, Vargas C, Schour L, Ghilezan M, Gustafson

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5. Public Accessibility

Transparency Tool URL: <https://akido.access.mcg.com/index>

Coverage Summaries URL: <https://www.myfamilymg.com/medical-necessity-supplementation-criteria/documents>

Navigation Instructions: To access these coverage summaries, navigate to the UM Criteria page, scroll to the bottom of the page, and click the Medical Necessity Supplementation Criteria link. All summaries are organized alphabetically by category.

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