Brachytherapy

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Link to Codes

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Clinical Indications

- Brachytherapy may be indicated for **1 or more** of the following:
  - Breast cancer, as indicated by **1 or more** of the following(25)(26)(27)(28)(29):N
    - Early-stage disease,[A] after treatment with lumpectomy[B]
    - Early-stage disease with high-risk features,[C] after treatment with lumpectomy,[D] and administered in conjunction with whole breast radiation
  - Cervical cancer[E](2)(34)(35)(36)N
  - Endometrial cancer[E](34)N
  - Esophageal cancer, and palliative treatment needed for dysphagia(45)(46)N
  - Head and neck cancer(1)N
  - Lung cancer, as indicated by **1 or more** of the following(56)(57)(58):N
    - Non-small cell lung cancer, and symptomatic recurrent disease, as indicated by **1 or more** of the following:
      - Endobronchial obstruction
      - Symptomatic hemoptysis
    - After local treatment failure with external beam radiation therapy, and recurrent symptoms, as indicated by **1 or more** of the following:
      - Atelectasis
      - Cough
      - Dyspnea
      - Hemoptysis
      - Postobstructive pneumonia
  - Nonmelanoma skin cancer (eg, basal cell carcinoma, squamous cell carcinoma) not amenable to surgery, or patient refuses surgery(62)(63)(64)N
  - Ocular melanoma[F] without evidence of distant metastasis (ie, confined to the globe)(68)(69)(70)N
  - Penile cancer(74)(75)(76)N
  - Prostate cancer,[G] as indicated by **1 or more** of the following(82)(83)(84)(85)(86):
    - Localized disease characterized as low risk, as indicated by **ALL** of the following[H](88)(89)(90):N
      - International Society of Urological Pathology (ISUP) Grade Group 1 (Gleason score of 6 or less)
      - Life expectancy 10 years or greater

- Pretreatment PSA less than 10 ng/mL (mcg/L)
- Stage T1 or T2a prostate cancer
- No active inflammatory bowel disease(83)

- Localized disease characterized as intermediate risk or high risk, as indicated by **ALL** of the following[H](4)(90)(96)(97):
  - Administered with or without concurrent external beam radiation
  - Clinical or pathologic features, as indicated by **1 or more** of the following:
    - ISUP Grade Group 2 to 5 (Gleason score of 7 to 10)
    - Pretreatment PSA of 10 ng/mL (mcg/L) or greater
    - Stage T2b or higher prostate cancer
  - Life expectancy greater than 5 years
- Local recurrence after primary radiation therapy

− Rectal cancer, as indicated by **1 or more** of the following(107)(108):
- Stage II or III disease that is medically operable, and **ALL** of the following:
  - Concurrent chemoradiation planned
  - Patient refuses abdominoperineal resection.
  - Tumor is less than 5 cm from anal verge.
- Stage II or III disease that is medically inoperable, and **1 or more** of the following:
  - Administered with chemoradiation, as indicated by **1 or more** of the following:
    - Tumor 10 cm or less from anal verge, and Eastern Cooperative Oncology Group (ECOG) performance status 0 to 1[J]
    - Tumor 10 cm or less from anal verge, Eastern Cooperative Oncology Group (ECOG) performance status 2 or higher,[I] and local symptoms present
    - Tumor less than 5 cm from anal verge, Eastern Cooperative Oncology Group (ECOG) performance status 2 or higher,[I] and local symptoms absent
  - Tumor 5 cm or less from anal verge, Eastern Cooperative Oncology Group (ECOG) performance status 0 to 1,[J] and local symptoms absent
  - Tumor 10 cm or less from anal verge and local symptoms present

− Retinoblastoma, as indicated by **ALL** of the following(73):
- After local treatment failure with **1 or more** of the following:
  - Chemotherapy
  - Cryotherapy
  - External beam radiation therapy
  - Laser therapy
- Clinical staging demonstrates no evidence of metastases.

- Soft tissue sarcoma(112)
- Vaginal cancer(118)(119)(120)

Alternatives

- Alternatives include:
  - Chemotherapy or immunotherapy
  - External beam radiation therapy
  - For esophageal cancer: self-expanding metal stents. See Esophagogastroduodenoscopy (EGD), UGI Endoscopy AC for further information.(45)(122)
  - For gynecologic cancer: intensity modulated radiation therapy. See Intensity Modulated Radiation Therapy (IMRT) AC for further information.
  - For head and neck cancer: intensity modulated radiation therapy or proton beam therapy. See Intensity Modulated Radiation Therapy (IMRT) AC or Proton Beam Therapy AC for further information.
  - For lung cancer, non-small cell: radiofrequency ablation of tumor or stereotactic body radiotherapy. See Radiofrequency Ablation of Tumor AC or Stereotactic Body Radiotherapy AC for further information.
  - For ocular melanoma: eye enucleation or proton beam therapy. See Proton Beam Therapy AC for further information.(70)(73)
  - For penile cancer: local excision or external beam radiation(74)(81)
  - For prostate cancer: radical prostatectomy, intensity modulated radiation therapy, or stereotactic body radiotherapy. See Intensity Modulated Radiation Therapy (IMRT) AC or Stereotactic Body Radiotherapy AC for further information.(82)(84)(85)
  - For soft tissue sarcoma: intensity modulated radiation therapy or radiofrequency ablation of tumor. See Intensity Modulated Radiation Therapy (IMRT) AC or Radiofrequency Ablation of Tumor AC for further information.
  - Three-dimensional conformal radiation therapy

Evidence Summary

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.(1)(2) **(EG 2)** High-dose-rate brachytherapy consists of the placement of thin catheters into the tumor. A radioactive pellet (eg, iridium) is sequentially introduced into each catheter and left in each position for a predetermined amount of time (usually several minutes) to allow for release of higher-dose radiation in a shorter period of time; no radioactive material is left permanently in the body.(3)(4)(5) **(EG 2)** Low-dose-rate brachytherapy is delivered via temporary or permanent implants and given as interstitial, intracavitary, intraluminal, and/or plesiotherapy (a radioactive mold for superficial lesions) to a variety of treatment sites.(6) **(EG 2)**

Criteria

The evidence for the clinical indications found in this guideline includes 80 published peer reviewed articles, 21 specialty society or other evidence-based guidelines, and 3 Cochrane systematic reviews.

For breast cancer, evidence demonstrates a net benefit, but of less than moderate certainty, and may consist of a consensus opinion of experts, case studies, and common standard care. **(RG A2)** A systematic review identified 3 randomized trials (5574 patients) that compared brachytherapy with whole breast radiotherapy after breast-conserving surgery for early-stage breast cancer and found no difference in overall survival.(26) **(EG 1)** A multicenter phase III noninferiority trial of 1184 breast cancer patients (stage 0, I, and IIA) concluded that 5-year local control, disease-free survival, and overall survival rates for accelerated partial breast irradiation using brachytherapy were not inferior to those for whole breast irradiation with tumor bed boost after lumpectomy.(28) **(EG 1)** An extension of this study found, at a median follow-up of 10.4 years, no difference in local recurrence rates between groups, and that accelerated partial breast irradiation was associated with fewer treatment-related grade 3 side effects compared with whole breast irradiation.(30) **(EG 1)** A single-center prospective study of 175 patients with early-stage breast cancer treated with accelerated partial breast irradiation delivered via multicatheter interstitial implant brachytherapy found, at a median follow-up of 10 years, ipsilateral breast cancer control, regional control, freedom from distant metastases, breast cancer-specific mortality, and overall mortality rates of 92.1%, 96.9%, 97.4%, 97.1%, and 81.2%, respectively.(31) **(EG 2)** A retrospective review of 364 patients with early-stage breast cancer treated with accelerated partial breast irradiation with high-dose-rate brachytherapy found 5-year and 10-year local relapse-free survival rates of 96.2% and 88.8%, respectively, and 5-year and 10-year overall survival rates of 95.1% and 92.2%, respectively.(32) **(EG 2)** An expert consensus guideline and a clinical practice guideline support the use of accelerated partial breast irradiation using brachytherapy after lumpectomy in patients age 40 years or older with estrogen receptor-positive stage T1 invasive ductal carcinoma with negative surgical margins or in low/intermediate screen-detected ductal carcinoma in situ measuring 3 cm or less with negative surgical margins.(25)(27) **(EG 2)** Another expert consensus guideline supports the use of accelerated partial breast irradiation using brachytherapy in patients age 45 years or older in tumors measuring 3 cm or less with invasive histology and ductal carcinoma in situ regardless of estrogen receptor status.(33) **(EG 2)**

For cervical cancer, evidence demonstrates at least moderate certainty of at least moderate net benefit. **(RG A1)** Practice guidelines recommend brachytherapy as a critical component of definitive treatment for all stages of disease.(2)(35)(37) **(EG 2)** A systematic review found that there were no significant differences between high-dose-rate and low-dose-rate intracavitary brachytherapy with regard to rates of overall survival, disease-free and relapse-free survival, local control rate, recurrence, and metastases. High-dose-rate intracavitary brachytherapy is recommended for all clinical stages of cervical cancer.(38) **(EG 1)** An analysis of 1719 women in a national cancer database (all with positive surgical margins after hysterectomy for cervical cancer) evaluating adjuvant radiation therapy with external beam radiation alone (941 patients) or combined with brachytherapy (778 patients) found that combination therapy was associated with improved 3-year overall survival.(39) **(EG 2)** An analysis of 630 women in a national cancer database (all with positive margins after hysterectomy for cervical cancer) evaluating adjuvant radiation therapy with external beam radiation alone (331 patients) or combined with brachytherapy (299 patients) found, at a median follow-up of 45.5 months, that combination therapy was associated with improved overall survival.(40) **(EG 2)** A consensus statement by a national brachytherapy specialty society recommends intraoperative high-dose-rate brachytherapy for cervical cancer with likely positive margins as well as for recurrent disease.(41) **(EG 2)**

For endometrial cancer, evidence demonstrates at least moderate certainty of at least moderate net benefit. **(RG A1)** An expert consensus guideline states that brachytherapy may be delivered to an intact uterus, either preoperatively or for definitive treatment, or more commonly, to the vagina after hysterectomy.(42) **(EG 2)** A specialty society guideline recommends adjuvant vaginal brachytherapy as a treatment option for patients with endometrial cancer limited to the uterus, cervix, or vaginal margins in order to prevent vaginal recurrence.(43) **(EG 2)** A systematic review and meta-analysis of 25 studies (2694 patients) of radiation therapy (brachytherapy alone or in combination with external beam radiation therapy) for treatment of inoperable endometrial carcinoma found 5-year local control and overall survival rates of 79.9% and 53.2%, respectively.(44) **(EG 1)** A consensus statement by a national brachytherapy specialty society recommends intraoperative high-dose-rate brachytherapy for uterine cancer with likely positive margins as well as for recurrent disease.(41) **(EG 2)**

For esophageal cancer and palliative treatment needed for dysphagia, evidence demonstrates a net benefit, but of less than moderate certainty, and may consist of a consensus opinion of experts, case studies, and common standard care. **(RG A2)** A systematic review and meta-analysis of 6 randomized prospective studies (623 patients) evaluating brachytherapy for dysphagia palliation found dysphagia-free survival of 86.9% at 1 month after treatment, which gradually decreased to 29.4% at 12 months post treatment. The

authors concluded that brachytherapy is an effective treatment option, although further randomized studies are recommended.(47) **(EG 1)** An expert consensus guideline states that brachytherapy is an alternative to external beam radiation therapy for treatment of malignant dysphagia. Although symptom relief is slower compared with endoscopic palliation, brachytherapy has more durable effects.(45) **(EG 2)** Evidence-based specialty society guidelines recommend brachytherapy alone or in combination with stenting for palliation of malignant dysphagia in patients with longer life expectancy.(46)(48) **(EG 2)**

For head and neck cancer, evidence demonstrates at least moderate certainty of at least moderate net benefit. **(RG A1)** Both low-dose-rate and high-dose-rate brachytherapy are endorsed by expert consensus guidelines and national radiology, therapeutic radiology, and oncology organizations for treatment of head and neck cancer, in particular cancer of the lip and oral cavity.(1)(49)(50)(51) **(EG 2)** A systematic review of 7 studies (456 patients) evaluating brachytherapy for the treatment of early-stage, node-negative oral cavity cancer found 5 year local control, disease-free survival, and overall survival rates of 60% to 100%, 82% to 91%, and 50% to 84%, respectively.(52) **(EG 1)** Retrospective studies involving patients with squamous cell carcinoma of the lip demonstrated that low-dose-rate and high-dose-rate brachytherapy are equivalent in terms of locoregional control and toxicity.(53)(54)(55) **(EG 2)**

For lung cancer, evidence demonstrates a net benefit, but of less than moderate certainty, and may consist of a consensus opinion of experts, case studies, and common standard care. **(RG A2)** A systematic review and meta-analysis of 15 studies (1188 patients) evaluating the efficacy of brachytherapy in advanced non-small cell lung cancer found that brachytherapy (alone or combined with chemotherapy) was associated with improved overall response and disease control rates, and brachytherapy combined with chemotherapy was associated with improved overall survival; patients treated with the combination had an increased risk of pulmonary complications (eg, pneumothorax, hemoptysis, pneumorrhagia).(59) **(EG 1)** A systematic review of 10 studies evaluating the efficacy of palliative brachytherapy (interstitial or endobronchial) for inoperable lung cancer found improvement in symptoms as well as good tolerability and endoscopic response rates.(60) **(EG 1)** A systematic review identified 3 randomized controlled trials that compared palliative treatment of non-small cell lung cancer with external beam radiation therapy vs endobronchial brachytherapy; results showed that external beam radiation therapy had greater effect on patients' symptoms, as assessed by both patients and physicians. Almost half of patients treated with endobronchial brachytherapy required later treatment with external beam radiation therapy. The authors concluded that endobronchial brachytherapy may be considered in patients previously treated with external beam radiation who develop recurrent symptoms of endobronchial obstruction.(58) **(EG 1)** A randomized trial of 134 patients with stage III or IV recurrent non-small cell lung cancer compared palliative treatment with external beam radiation therapy alone or combined with high-dose-rate intraluminal brachytherapy and found, at a mean follow-up of 7.4 months, that brachytherapy was associated with improvement in hemoptysis compared with radiation therapy alone; no differences in other symptoms, progression-free survival, or overall survival were seen between groups.(61) **(EG 1)** A specialty society's appropriate-use criteria state that endobronchial brachytherapy can be used for the palliation of obstructive symptoms (eg, hemoptysis, postobstructive pneumonia, atelectasis, dyspnea, cough) in non-small cell lung cancer.(57) **(EG 2)** An expert consensus guideline indicates that brachytherapy may be an appropriate intervention for treatment of endobronchial obstruction or hemoptysis resulting from recurrent local or locoregional disease.(56) **(EG 2)**

For nonmelanoma skin cancer, evidence demonstrates a net benefit, but of less than moderate certainty, and may consist of a consensus opinion of experts, case studies, and common standard care. **(RG A2)** A systematic review and meta-analysis of 24 studies (10,518 patients) comparing external beam radiation therapy with brachytherapy for management of nonmelanoma skin cancer found that at higher total radiation doses (biological equivalent doses of 100 to 120 total Gy), brachytherapy was associated with more patients achieving good cosmetic results. However, the authors noted that, due to a relative lack of brachytherapy studies and short follow-up times, further prospective studies comparing different radiation modalities are required.(65) **(EG 1)** Expert consensus guidelines indicate that brachytherapy can be an effective therapy for cutaneous basal and squamous cell carcinoma, particularly on the head and neck.(62)(63) **(EG 2)** A specialty society guideline states that radionuclide brachytherapy is a standard-of-care option for cutaneous basal and squamous cell carcinoma when surgery is contraindicated because of medical comorbidities, when surgery may lead to adverse functional or cosmetic outcomes because of a tumor's location, and in patients who refuse surgery.(66) **(EG 2)**

For ocular melanoma, evidence demonstrates at least moderate certainty of at least moderate net benefit. **(RG A1)** A multicenter randomized controlled trial with 1317 patients reported that brachytherapy is an acceptable alternative to eye enucleation and does not adversely affect long-term survival.(70) **(EG 1)** An analysis of a national cancer database compared plaque brachytherapy or proton beam therapy in 1224 patients with choroid melanoma and found, at 5-year follow-up, that brachytherapy was associated with improved overall survival rates (81% and 54% in the brachytherapy and proton beam therapy groups, respectively).(71) **(EG 2)** A retrospective review of 82 patients with medium-sized choroidal melanoma treated with iodine-125 episcleral plaque brachytherapy reported globe preservation of 97.6%; local recurrence and metastatic disease developed in 2.4% and 11% of patients, respectively.(72) **(EG 2)** A specialty society consensus guideline supports the use of plaque brachytherapy for uveal melanoma.(73) **(EG 2)**

For penile cancer, evidence demonstrates at least moderate certainty of at least moderate net benefit. **(RG A1)** A meta-analysis of 20 retrospective studies (including 2178 men) comparing surgery with brachytherapy found comparable overall survival at 5 years, although penectomy was associated with a better rate of local control (84% vs 79%, respectively).(77) **(EG 1)** A retrospective review of 201 men treated with brachytherapy for penile carcinoma found, at 5-year follow-up, overall survival and local control rates of 79% and 82%, respectively. Among patients surviving 5 years, the penile preservation rate was 85%.(78) **(EG 2)** A retrospective review of 76 patients treated with brachytherapy for penile carcinoma found, at 5-year and 10-year follow-up, overall survival rates of 76.5% and 57.8%, respectively; cause-specific survival rates of 85% and 77.8%, respectively; penile preservation rates of 69.5% and 66.9%, respectively; and local control rates of 65.6% and 65.6%, respectively.(79) **(EG 2)** A review article notes that patients with T1b or T2 disease less than 4 cm that is confined to the glans penis may be treated with high-dose-rate brachytherapy as an organ-sparing approach.(80) **(EG 2)** Expert consensus guidelines state that brachytherapy may be used as primary or postoperative adjuvant therapy.

(74)(81) **(EG 2)** Consensus and specialty society guidelines recommend brachytherapy as initial therapy for invasive squamous cell carcinoma (T1, T2, and selected T3 penile cancers), citing good tumor control rates, acceptable morbidity, and functional organ preservation.(75)(76) **(EG 2)**

For prostate cancer characterized as low risk, evidence demonstrates at least moderate certainty of at least moderate net benefit. **(RG A1)** Practice guidelines state that low-dose-rate brachytherapy is a treatment option for low-risk prostate cancer.(82)(83)(84)(91) **(EG 2)** A prospective study of 156 patients with localized low-risk prostate cancer (30 patients were randomly assigned; the remaining patients self-selected their treatment) compared treatment with either radical prostatectomy or low-dose-rate brachytherapy and found that brachytherapy was associated with a lower incidence of biochemical failure (defined as a PSA of 0.5 ng/mL (mcg/L) or greater) compared with prostatectomy at a median follow-up of 12.6 to 14.7 years; no difference in prostate cancer-specific mortality was seen between groups.(92) **(EG 2)** An observational study of 1038 men with low-risk prostate cancer (ie, Gleason Grade score of 6, PSA less than or equal to 10 ng/mL (mcg/L), clinical stage T2b or less) treated with low-dose-rate brachytherapy found, at a median follow-up of 5 years, that biochemical relapse-free survival was 94%.(93) **(EG 2)** A study of 809 patients comparing those who met standard criteria for low-risk prostate cancer (ie, Gleason Grade score of 6 or less and PSA of less than 10 ng/mL (mcg/L)) with patients who did not meet criteria (defined as a PSA level between 10 ng/mL (mcg/L) and 15 ng/mL (mcg/L) or a Gleason score of 7, or both) reported that there was a statistically significant difference in 5-year relapse-free survival (97% vs 94%) in the group that met criteria. Subgroup analysis demonstrated a 5-year relapse-free survival of 88% for patients with a Gleason score of 7 and PSA greater than 10 ng/mL (mcg/L).(89) **(EG 2)** A matched-pair analysis of 278 patients (139 in each group) comparing brachytherapy with external beam radiation therapy reported that, at 5-year follow-up, there was no biochemical evidence of disease in 95% of the brachytherapy group as compared with 85% in the external beam radiation therapy group. Follow-up at 7 years demonstrated that the biochemical evidence of disease had not changed in the brachytherapy group but had fallen to 75% in the external beam radiation therapy group. However, late urinary toxicity and rectal/bowel toxicity were worse in patients treated with brachytherapy.(94) **(EG 1)** A retrospective review of 423 patients (all age 60 years or younger) with localized prostate cancer treated with brachytherapy with or without external beam radiation therapy found 10-year and 15-year freedom from biochemical failure rates of 89% and 88%, respectively, and cancer-specific survival rates of 99% and 98%, respectively.(95) **(EG 2)**

For prostate cancer characterized as high risk, evidence demonstrates at least moderate certainty of at least moderate net benefit. **(RG A1)** A systematic review and meta-analysis of 3 randomized trials (703 patients with intermediate-risk or high-risk prostate cancer) comparing boost therapy with brachytherapy or external beam radiotherapy (EBRT) after initial radiotherapy found, at 5-year follow-up, that brachytherapy boost was associated with improved biochemical progression-free survival compared with EBRT boost, with no difference in overall survival seen between the groups.(98) **(EG 1)** A randomized trial of 579 patients with intermediate-risk prostate cancer compared treatment with brachytherapy alone or combined with EBRT and found no difference in rates of 5-year freedom from progression between the groups.(99) **(EG 1)** A retrospective study of 1809 patients with prostate cancer with a Gleason score of 9 to 10 compared treatment with radical prostatectomy, EBRT plus androgen deprivation therapy (EBRT-ADT), and EBRT-ADT plus brachytherapy and found that the brachytherapy arm was associated with better prostate cancer-specific mortality and longer time to distant metastases.(100) **(EG 2)** A retrospective study of 20,279 patients with intermediate-risk and high-risk prostate cancer found that, at a median follow-up of 82 months, combination treatment with brachytherapy plus EBRT was associated with improved survival compared with treatment with EBRT alone.(101) **(EG 2)** An analysis of 122,896 patients in a national cancer database (all with intermediate-risk or high-risk prostate cancer) compared treatment with brachytherapy (high-dose-rate or low-dose-rate) or dose-escalated EBRT and found that brachytherapy at either dose rate was associated with longer overall survival compared with EBRT.(102) **(EG 2)** An analysis of 32,246 patients in a national cancer database (all with intermediate-risk or high-risk prostate cancer) compared treatment with either EBRT alone, EBRT-ADT, EBRT combined with brachytherapy, or EBRT combined with both ADT and brachytherapy and found, at a median follow-up of 60 months, that the addition of brachytherapy (with or without ADT) was associated with improved overall survival compared with EBRT alone or EBRT-ADT.(103) **(EG 2)** Practice guidelines state that an appropriate treatment option for high-risk prostate cancer is delivery of high-dose-rate brachytherapy as a boost in conjunction with EBRT to the pelvis (either with or without neoadjuvant ADT).(84)(96)(104)(105) **(EG 2)**

For prostate cancer, local recurrence, evidence demonstrates at least moderate certainty of at least moderate net benefit. **(RG A1)** An expert consensus guideline indicates that brachytherapy (permanent low-dose-rate or temporary high-dose-rate) may be used for local recurrence of prostate cancer following external beam radiation therapy or primary brachytherapy.(82) **(EG 2)** A prospective study of 37 men with biopsy-proven local recurrence following radiotherapy, with a median follow-up of 86 months, reported a 10-year actuarial freedom from biochemical failure of 54% and a cause-specific survival of 96% following salvage brachytherapy.(106) **(EG 2)**

For rectal cancer, evidence demonstrates a net benefit, but of less than moderate certainty, and may consist of a consensus opinion of experts, case studies, and common standard care. **(RG A2)** A randomized phase III trial of 141 patients with operable rectal adenocarcinoma compared treatment with chemoradiotherapy (external beam radiation plus oral capecitabine) followed by a boost with either external beam radiotherapy or x-ray brachytherapy and found, at a median follow-up of 38.2 months, that brachytherapy was associated with a higher organ preservation rate (defined as avoidance of mesorectal excision) compared with external beam radiotherapy.(109) **(EG 1)** An observational study of 221 patients with rectal cancer randomized to chemoradiation therapy with or without a brachytherapy boost found, at a median follow-up of 5.4 years, that there were no significant differences between groups with regard to overall and progression-free survival rates and freedom from locoregional and distant metastases.(110) **(EG 2)** A specialty society consensus practice guideline states that brachytherapy alone may be appropriate for medically inoperable stage II or III rectal cancers if the tumor is 10 cm or less from the anal verge. Brachytherapy combined with chemoradiation may be appropriate for medically inoperable stage II or III cancers in all patients with good Eastern Cooperative Oncology Group (ECOG) performance (0 to 1), in locally symptomatic patients with poor ECOG performance (2 or higher) if the tumor is 10 cm or less from the anal verge, and in

locally asymptomatic patients with poor ECOG performance (2 or higher) whose tumor is less than 5 cm from the anal verge. For patients with medically operable, low-lying (less than 5 cm from the anal verge) stage II or III rectal cancer who refuse abdominoperineal resection, brachytherapy combined with chemoradiation may be appropriate.(108) **(EG 2)** A consensus statement by a national brachytherapy specialty society recommends intraoperative high-dose-rate brachytherapy for colorectal cancer with likely positive margins as well as for recurrent disease.(41) **(EG 2)**

For retinoblastoma, evidence demonstrates a net benefit, but of less than moderate certainty, and may consist of a consensus opinion of experts, case studies, and common standard care. **(RG A2)** A specialty society consensus guideline supports the use of plaque brachytherapy for treatment of retinoblastoma.(73) **(EG 2)**

For soft tissue sarcoma, evidence demonstrates at least moderate certainty of at least moderate net benefit. **(RG A1)** A prospective study of 106 adult patients with extremity or superficial trunk soft tissue sarcomas treated with perioperative high-dose-rate brachytherapy combined with postoperative external beam radiotherapy found 10-year disease-free and overall survival rates of 59% and 62%, respectively.(113) **(EG 2)** A retrospective study of 93 patients with unresectable metastatic soft tissue sarcoma (all of whom progressed despite first-line chemotherapy) compared treatment with second-line chemotherapy with and without brachytherapy and found that brachytherapy was associated with prolonged progression-free survival, and improved local disease control at 6, 12, 24, and 36 months' follow-up, compared with chemotherapy alone.(114) **(EG 2)** A prospective study of 100 pediatric patients (median age 28 months) with bladder and/or prostate rhabdomyosarcoma evaluated brachytherapy as part of multimodal management (including conservative surgery and chemotherapy) and found, at a median follow-up of 64 months, 5-year disease-free and overall survival rates of 84% and 91%, respectively.(115) **(EG 2)** A retrospective study of 105 pediatric patients (median age 10 years) with soft tissue sarcoma treated with wide excision and brachytherapy (with or without external beam radiotherapy) found 5-year local control, disease-free, and overall survival rates of 87%, 70%, and 77%, respectively, and 10-year local control, disease-free, and overall survival rates of 83%, 66%, and 73%, respectively.(116) **(EG 2)** Practice guidelines recommend brachytherapy as an integral component of management of soft tissue sarcoma. Applications include definitive therapy, postoperative adjuvant therapy, intraoperative radiotherapy, and palliative therapy. Low-dose-rate and high-dose-rate brachytherapy have been shown to achieve similar local control.(1)(112) **(EG 2)** A consensus statement by a national brachytherapy specialty society concludes that brachytherapy is an essential component of soft tissue sarcoma treatment, citing a more targeted dose distribution that minimizes radiation exposure of normal tissue, a low integral dose, and shorter treatment times.(117) **(EG 2)** A consensus statement by a national brachytherapy specialty society recommends intraoperative high-dose-rate brachytherapy for soft tissue sarcoma to limit local recurrence when visualization of the tumor bed is possible, especially when the surgical margins are likely to be positive.(41) **(EG 2)**

For vaginal cancer, evidence demonstrates at least moderate certainty of at least moderate net benefit. **(RG A1)** Brachytherapy, with or without external beam radiotherapy, is used for curative therapy of vaginal cancer.(1)(118)(120) **(EG 2)** An analysis of a national cancer database of 1094 patients with vaginal cancer compared treatment with combination chemotherapy plus external beam radiotherapy with and without a brachytherapy boost and found that the addition of brachytherapy was associated with improved overall survival compared with chemotherapy and external beam radiotherapy alone.(121) **(EG 2)** A consensus statement by a national brachytherapy specialty society recommends intraoperative high-dose-rate brachytherapy for vaginal cancer with likely positive margins as well as for recurrent disease.(41) **(EG 2)**

Inconclusive or Non-Supportive Evidence

For anal cancer, evidence is insufficient, conflicting, or poor and demonstrates an incomplete assessment of net benefit vs harm; additional research is recommended. **(RG B)** A systematic review of 10 cohort and retrospective studies of high-dose-rate brachytherapy for anal cancer (448 patients treated with external beam radiation therapy, of whom 371 received a brachytherapy boost) found, at a mean follow-up of 39.9 months, complete response rates ranging from 79.5% to 100%, local control rates ranging from 81% to 94%, pooled mean local failure rate of 12.3% (9 studies), weighted mean 5-year disease-free survival of 77.5% (5 studies), and weighted mean overall survival of 81.9% (4 studies). However, the authors noted that the lack of randomized trials, heterogeneity among the included trials, and the relatively small number of patients limited the results; further large randomized studies were recommended.(7) **(EG 1)** A specialty society guideline states that there is currently limited evidence regarding the use of brachytherapy for anal cancer and recommends randomized controlled trials to study the optimal dosing and appropriate delivery modality of radiation therapy in anal cancer treatment.(8) **(EG 2)** An expert consensus guideline does not include brachytherapy as a treatment option in the management of anal cancer.(9) **(EG 2)**

For bone and spinal metastases, evidence is insufficient, conflicting, or poor and demonstrates an incomplete assessment of net benefit vs harm; additional research is recommended. **(RG B)** A systematic review of 14 studies with 689 patients (13 studies included in meta-analysis) evaluating the efficacy of brachytherapy for bone and spine metastases found, at 4-week and 24-week follow-up, that brachytherapy was associated with improvement in pain from baseline, especially when combined with cement augmentation. However, half of the included studies were retrospective, and the authors noted that the relatively short follow-up period and heterogeneity among included studies in treatment outcomes and patient populations limited the results; further prospective randomized trials were recommended.(10) **(EG 1)**

For brain cancer, evidence is insufficient, conflicting, or poor and demonstrates an incomplete assessment of net benefit vs harm; additional research is recommended. **(RG B)** A systematic review and meta-analysis evaluating the use of brachytherapy for glioblastoma multiforme identified 18 studies (811 patients) of newly diagnosed disease and found progression-free and overall survival of 15 months and 28.5 months, respectively. Adverse events occurred in 27% of patients, and most of those events were grade 4

radiation necrosis that presented with new or worsening neurologic deficits. However, the authors noted variability in outcomes across studies and stated that the most effective use of brachytherapy may be as part of multimodality treatment.(11) **(EG 1)** A systematic review of 29 studies (1202 patients) evaluating the efficacy of brachytherapy as salvage therapy in patients with recurrent glioblastoma multiforme found, from the start of brachytherapy, median overall survival of 6.8 to 24.4 months and median progression-free survival of 3.7 to 11.7 months. The authors noted that the retrospective design of most of the studies and heterogeneity in brachytherapy techniques used limited the results.(12) **(EG 1)** Iodine-125 brachytherapy has been utilized in the treatment of various types of brain tumors, including astrocytomas, brainstem gliomas, glioblastomas, and metastatic disease.(13)(14) **(EG 2)** Additional evidence from prospective randomized clinical trials is required before the role of iodine-125 brachytherapy of various brain malignancies is clearly defined.(13)(14) **(EG 2)** A retrospective review of 119 patients with brain tumors (metastases, gliomas, or meningiomas) treated with cesium-131 brachytherapy found 1-year survival rates of 53.3%, 45.9%, and 73.3% for metastases, gliomas, and meningiomas, respectively, and 1-year local control rates of 84.7%, 34.1%, and 83.3% for metastases, gliomas, and meningiomas, respectively.(15) **(EG 2)**

For hepatobiliary cancer, evidence is insufficient, conflicting, or poor and demonstrates an incomplete assessment of net benefit vs harm; additional research is recommended. **(RG B)** A systematic review found that there are no randomized trials for the treatment of extrahepatic bile duct carcinoma with brachytherapy. Studies show conflicting outcomes with regard to a possible survival benefit when brachytherapy is utilized as adjuvant therapy after surgical resection; its effectiveness as a stand-alone treatment for inoperable tumors is limited due to the high rate of local recurrence in nonirradiated portions of the bile duct. Additional studies were recommended.(16) **(EG 1)** An exploratory phase II randomized trial of 77 patients with unresectable hepatocellular carcinoma compared single or repeated treatment with brachytherapy or transarterial chemoembolization (TACE) and found, at 1-year, 2-year, and 3-year follow-up, that brachytherapy was associated with longer time to untreatable progression (defined as time from first treatment to when tumor ablation with the assigned technique was no longer possible) and longer time to progression compared with TACE, with no difference in overall survival seen between the groups. However, the authors noted that the small number of patients limited the results, and further studies were recommended.(17) **(EG 1)** An expert consensus guideline does not include brachytherapy as a treatment option in the management of hepatobiliary cancers.(18)(19) **(EG 2)**

For malignant obstructive jaundice, evidence is insufficient, conflicting, or poor and demonstrates an incomplete assessment of net benefit vs harm; additional research is recommended. **(RG B)** A systematic review of 17 studies including 649 patients with obstructive jaundice due to cholangiocarcinoma (4 studies with 112 patients included in meta-analysis) comparing biliary stenting with and without intraluminal brachytherapy found that brachytherapy was associated with longer stent patency and median overall survival compared with no brachytherapy. However, the authors noted that the retrospective design of several included studies, the small number of included patients, and heterogeneity among studies limited the results, and larger randomized trials were recommended.(20) **(EG 1)** A systematic review and meta-analysis of 12 studies (641 patients) comparing biliary stenting with and without intraluminal brachytherapy for malignant obstructive jaundice found that brachytherapy was associated with lower rates of stent occlusion and improved patient survival without an increase in complications. However, the authors noted that, due to the retrospective nature of 7 of the included trials, significant heterogeneity among studies, and inclusion of multiple malignant pathologies, further randomized trials were needed.(21) **(EG 1)**

For vulvar cancer, evidence is insufficient, conflicting, or poor and demonstrates an incomplete assessment of net benefit vs harm; additional research is recommended. **(RG B)** A systematic review of 9 retrospective studies evaluating brachytherapy with or without external radiation therapy for the management of vulvar cancer found, among 129 patients with primary disease, median 5-year local control, disease-free survival, and overall survival rates of 43.5%, 44.5%, and 50.5%, respectively, and among 13 patients with recurrent disease, median 5-year disease-free and overall survival rates of 64% and 45%, respectively. However, the authors noted that the retrospective nature of the included studies, the small number of patients, the relatively short follow-up time, and heterogeneity among the included studies limited the results, and further studies were recommended.(22) **(EG 1)** A narrative review notes that there is evidence from small observational studies that supports the effectiveness of brachytherapy for vulvar cancer and that higher-quality prospective data are needed.(23) **(EG 2)** An expert consensus guideline states that brachytherapy combined with external beam radiation therapy with or without concurrent chemotherapy is a treatment option for recurrent disease confined to the vulva.(24) **(EG 2)**

Rationale

Use of this MCG care guideline helps the clinician determine if a particular treatment, medication, or service might be appropriate for a specific patient, taking into account their unique health complexities.

Use of these evidence-based clinical criteria to support decision making benefits the patient by identifying patient-specific complex clinical factors and conditions, promoting personalized treatment. Utilizing evidence-based clinical criteria promotes patient safety by helping ensure that potential patient benefits outweigh the risks. In addition, the use of evidence-based guidelines can increase consistency in treatment thresholds, leading to less variation in care and promoting equitable treatment among patients.

Related CMS Coverage Guidance

This guideline supplements but does not replace, modify, or supersede existing Medicare regulations or applicable National Coverage Determinations (NCDs) or Local Coverage Determinations (LCDs).

Code of Federal Regulations (CFR): 42 CFR 419.22(123); 42 CFR 422.101(124)

Internet-Only Manual (IOM) Citations: CMS IOM Publication 100-02, Medicare Benefit Policy Manual, Chapter 14 - Medical Devices(125); CMS IOM Publication 100-02, Medicare Benefit Policy Manual, Chapter 15 - Covered Medical and Other Health Services(126); CMS IOM Publication 100-02, Medicare Benefit Policy Manual, Chapter 16 - General Exclusions from Coverage(127)

Medicare Coverage Determinations: Medicare Coverage Database(128)

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Footnotes

[A] Early-stage disease is defined as invasive ductal carcinoma in patients age 40 years or older with all of the following pathologic characteristics: negative surgical margin, no lymphovascular invasion, tumor size 3 cm or less, and 3 or fewer lymph nodes. Low-grade or intermediate-grade ductal carcinoma in situ with negative surgical margin width of 2 mm or greater and tumor size 3 cm or less is also considered early-stage disease.(27)(33) [A in Context Link 1]

[B] Accelerated partial breast irradiation is a localized form of radiation therapy delivered after lumpectomy to the part of the breast where the tumor was removed. It can be performed using brachytherapy or external beam radiation therapy.(27) [B in Context Link 1]

[C] High-risk features include patient age younger than 40 years, focally positive surgical margins, or high-grade (poorly differentiated) disease.(25)(27)(33) [C in Context Link 1]

[D] Boost therapy is radiation treatment to the tumor bed after lumpectomy given in addition to whole breast radiation. It can be given via brachytherapy, electron beam, or photon field.(25) [D in Context Link 1]

[E] For gynecologic cancers, brachytherapy involves placement of an intrauterine device or a vaginal cylinder, ovoid, or ring device to selectively deliver higher doses of radiation to the tumor while minimizing the dose delivered to other pelvic organs.(2)(34) [E in Context Link 1, 2]

[F] For ocular melanoma, brachytherapy involves surgical placement of an episcleral plaque impregnated with radioactive iodine, palladium, ruthenium, or cesium to destroy tumor cells and preserve other ocular structures.(67)(68)(69) The plaque is surgically removed within 5 to 7 days, after appropriate dosimetry calculation.(67) [F in Context Link 1]

[G] For prostate cancer, brachytherapy involves placement of temporary (high-dose-rate) or permanent (low-dose-rate) radioactive iodine or palladium seeds into the prostate tissue in a single outpatient session.(82) [G in Context Link 1, 2]

[H] Patients with very large prostates (volume greater than 60 mL) are generally considered suboptimal candidates for brachytherapy because of higher risk for developing postoperative urinary retention; small prostate size (volume 20 mL or less) is considered a relative contraindication because of the difficulty of performing a good implant. Patients with symptoms of bladder outlet obstruction and patients with previous transurethral resection of prostate are not ideal candidates for brachytherapy.(82)(87) [H in Context Link 1, 2]

[I] An Eastern Cooperative Oncology Group (ECOG) performance status of 2 signifies a patient who is ambulatory and capable of all self-care, and up and about for more than 50% of waking hours, but unable to carry out any work activities. An ECOG performance status of 3 signifies a patient who is capable of only limited self-care and confined to bed or chair for more than 50% of waking hours. An ECOG performance score of 4 signifies a patient who is completely disabled, unable to carry out any self-care, and totally confined to bed or chair. An ECOG performance score of 5 signifies a patient who is dead.(111) [I in Context Link 1, 2]

[J] An Eastern Cooperative Oncology Group (ECOG) performance status of 0 signifies a patient who is fully active and able to carry on all predisease performance without restriction. An ECOG performance status of 1 signifies a patient who is restricted in physically strenuous activity but ambulatory and able to carry out work of a light or sedentary nature.(111) [J in Context Link 1, 2]

Codes

CPT®: 19296, 19297, 19298, 20555, 32553, 41019, 49327, 49411, 49412, 55860, 55875, 55876, 55920, 57155, 57156, 58346, 61770, 67218, 76942, 77002, 77012, 77021, 77261, 77262, 77263, 77280, 77285, 77290, 77295, 77300, 77316, 77317, 77318, 77321, 77331, 77332, 77333, 77334, 77336, 77370, 77387, 77417, 77427, 77431, 77470, 77750, 77761, 77762, 77763, 77767, 77768, 77770, 77771, 77772, 77778, 77789, 77790, 77799 [Hide]

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