National Imaging Associates, Inc.*

2023 NIA Clinical Guidelines For Medical Necessity Review

RADIATION ONCOLOGY GUIDELINES
Effective January 1, 2023 – December 31, 2023

*National Imaging Associates, Inc. (NIA) is a subsidiary of Evolent Health, LLC.
 Guidelines for Clinical Review Determination

Preamble
NIA is committed to the philosophy of supporting safe and effective treatment for patients. The medical necessity criteria that follow are guidelines for the provision of diagnostic imaging. These criteria are designed to guide both providers and reviewers to the most appropriate diagnostic tests based on a patient’s unique circumstances. In all cases, clinical judgment consistent with the standards of good medical practice will be used when applying the guidelines. Determinations are made based on both the guideline and clinical information provided at the time of the request. It is expected that medical necessity decisions may change as new evidence-based information is provided or based on unique aspects of the patient’s condition. The treating clinician has final authority and responsibility for treatment decisions regarding the care of the patient.

Guideline Development Process
These medical necessity criteria were developed by National Imaging Associates, Inc. (NIA) for the purpose of making clinical review determinations for requests for therapies and diagnostic procedures. The developers of the criteria sets included representatives from the disciplines of radiology, internal medicine, nursing, cardiology, and other specialty groups. NIA’s guidelines are reviewed yearly and modified when necessary following a literature search of pertinent and established clinical guidelines and accepted diagnostic imaging practices.

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Most requests for radiation therapy are addressed by NIA treatment site clinical guidelines. However, there may be requests that are not. For such requests, determinations will be made on a case-by-case basis utilizing the following guidelines (when applicable) but not limited to: National Comprehensive Cancer Network (NCCN), American Society for Radiation Oncology ASTRO (i.e., Model Policies; Evidence-Based Consensus Statement), ACR Appropriateness Criteria, American Society of Clinical Oncology (ASCO) and/or peer reviewed literature.

This guideline for 2D – 3D CRT applies to other cancers not addressed by NIA treatment site clinical guidelines.

Refer to applicable treatment site-specific guidelines for the management of primary malignancies. Applicable site-specific guidelines may include all or some of the sites below, depending on the specific program.

• Anal Cancer
• Bone Metastases
• Breast Cancer
• Cervical Cancer
• CNS Cancer
• Colon Cancer
• Rectal Cancer
• Endometrial Cancer

• Gastric Cancers
• Head and Neck Cancer
• Lung - Non Small Cell
• Lung - Small Cell Lung Cancer
• Lymphoma - Hodgkin’s Lymphoma
• Lymphoma - Non-Hodgkin’s Lymphoma
• Pancreas Cancer
• Prostate Cancers

For metastasis to the brain, regardless of primary site, refer to the NIA clinical guideline for Central Nervous System (CNS). For metastasis to bone, refer to the NIA clinical guideline for Bone Metastases. For all other metastases, refer to the NIA clinical guideline for metastatic disease.
INDICATIONS FOR 2D – 3D CRT

OTHER CANCER SITES NOT LISTED ABOVE

- Conventional 2D and 3D-CRT treatment delivery is appropriate for all primary malignancies not listed above.
- The number of fractions for definitive treatment is approvable up to 30 fractions. Fractions beyond 30 may be approvable upon physician review when clinical rationale is presented.

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<td>For clarity, moved the list of applicable site-specific guidelines from the background section to precede the indications (similar to other guidelines, such as brachytherapy and IMRT).</td>
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Reviewed / Approved by NIA Clinical Guideline Committee
GENERAL INFORMATION

It is an expectation that all patients receive care/services from a licensed clinician. All appropriate supporting documentation, including recent pertinent office visit notes, laboratory data, and results of any special testing must be provided. If applicable: All prior relevant imaging results and the reason that alternative imaging cannot be performed must be included in the documentation submitted.

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INDICATIONS FOR RADIATION THERAPY

2D, 3D-CRT and IMRT are all appropriate techniques for treatment of anal cancer. Electron beam or photon beam are the most commonly used techniques for delivering boost radiotherapy.¹

- Dosage Guidelines: 45Gy – 59.4Gy in 28 to 33 fractions

Unless otherwise indicated, standard radiation fractionation consists of 1.8 Gy to 2.0 Gy per day

TREATMENT OPTIONS REQUIRING PHYSICIAN REVIEW

Proton Beam Radiation Therapy
Proton beam is not an approved treatment option for anal cancer. Proton beam has not been proven superior treatment to conventional radiation therapy.

Stereotactic Body Radiation Therapy (SBRT)
Stereotactic Body Radiation Therapy is not a standard treatment option for the treatment of anal cancer. A peer review is required with a radiation oncologist.

THE FOLLOWING APPLIES TO CMS (MEDICARE) MEMBERS ONLY
For Proton Beam and Stereotactic Radiotherapy, refer to Local Coverage Determination (LCD), if applicable.

BACKGROUND
This guideline outlines methods suitable for delivering anal carcinoma radiation therapy. Techniques such CT simulation, conformal approach, and intensity modulated radiation therapy (IMRT) have shown promising results in ongoing clinical trials. IMRT use requires expertise in defining appropriate

¹—Anal Cancer
target volume over conventional conformal beam irradiation. As in most cancers, a multidisciplinary approach is preferred for treating patients with anal carcinoma.

POLICY HISTORY

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ADDITIONAL RESOURCES


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MEDICALLY NECESSARY INDICATIONS FOR RADIATION THERAPY

2D or 3D Conformal External Beam Radiation Therapy (EBRT) is appropriate for the treatment of bone metastases

**Good performance status = ECOG less than 3:**
- EBRT – Up to 10 fractions for multiple bone metastases

**Poor performance status = ECOG 3 or greater or progressive metastatic disease:**
- EBRT – Up to 5 fractions

All other treatment regimens require physician review.

TREATMENT OPTIONS REQUIRING PHYSICIAN REVIEW

Intensity modulated radiation therapy (IMRT)

IMRT is not indicated as a standard treatment option and should not be used routinely for the delivery of radiation therapy for bone metastasis. IMRT may be appropriate for limited circumstances in which radiation therapy is indicated and 3D conformal radiation therapy (3D-CRT) techniques cannot adequately deliver the radiation prescription without exceeding normal tissue radiation tolerance, the delivery is anticipated to contribute to potential late toxicity or tumor volume dose heterogeneity is such that unacceptable hot or cold spots are created.

Requests for IMRT require physician review of the clinical rationale and documentation for performing IMRT rather than 2D or 3D-CRT treatment planning and delivery. Supporting documentation will need to:

- Demonstrate how 3D-CRT isodose planning cannot produce a satisfactory treatment plan (as stated above) via the use of patient-specific dose volume histograms and isodose plans.

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• Provide tissue constraints for both the target and affected critical structures.

**Stereotactic Body Radiation Therapy (SBRT)**

Stereotactic Body Radiation Therapy (SBRT) for treatment of bone metastasis may be medically necessary to treat previously irradiated field.¹

• Oligometastatic Disease*: Stereotactic Body Radiation Therapy (SBRT) is medically necessary for extracranial oligometastatic disease for an individual with One (1) to Five (5) metastatic lesions when the following criteria are met:
  o Good performance status: ECOG less than 3 or Karnofsky Scale greater than or equal to 70% and stable systemic disease or reasonable systemic treatment options.

*Note: Based on available data, OMD can to date be defined as 1–5 metastatic lesions, a controlled primary tumor being optional, but where all metastatic sites must be safely treatable.²

**Proton Beam Radiation Therapy**

Proton beam is not an approved treatment option for bone metastasis. Overall, studies of proton beam therapy have not shown clinical outcomes to be superior to conventional radiation therapy in bone metastases.

**THE FOLLOWING APPLIES TO CMS (MEDICARE) MEMBERS ONLY**

*For Proton Beam and Stereotactic Radiotherapy refer to Local Coverage Determination (LCD), if applicable.*

**BACKGROUND**

Bone metastases are a common manifestation of malignancy that can cause severe and debilitating effects including pain, spinal cord compression, hypercalcemia, and pathologic fracture. Radiation therapy has a proven track record in the palliation of bone metastases. Following a course of palliative treatment, approximately one-third of patients will have complete relief of pain, and two-thirds of patients will have significant reduction in their pain. The optimal delivery of radiation therapy has been the focus of multiple trials looking at the best dose fractionation. Common dose fractionation schedules have shown good rates of palliation, including 8 Gy in 1 fraction, 20 Gy in 4 fractions, 24 Gy in 6 fractions, or 30 Gy in 10 fractions. All provide excellent pain control with minimal side effects. The benefit of the single fraction is that it is the most convenient for patients, whereas the advantage of a longer course of treatment is a lower incidence of re-treatment to the same site. Dose fractionation is typically determined based on location of the metastasis, patient’s clinical status, previous irradiation treatment, etc. Therefore, multiple factors must be reviewed prior to prescribing palliative radiotherapy.
### POLICY HISTORY

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| January 2022  | - In SBRT, increased the range for the number of metastatic lesions from One (1) to Four (4) to One (1) to Five (5)  
                - In SBRT, added Note to clarify oligometastatic disease              |
| February 2021 | 1. **MEDICALLY NECESSARY INDICATIONS FOR RADIATION THERAPY**   
                Deleted:  
                • Conventional 2D planning techniques is appropriate for the treatment of bone metastases.  
                • 3D-CRT may be indicated in select cases such as situations of re-treatment, overlapping volumes or adjacent critical structures that are likely to cause complications. Requests for 3D-CRT must be accompanied by supporting clinical rationale.  
                Favorable Risk (Good performance status = ECOG less than 3):  
                • EBRT – Up to 10 fractions for multiple bone metastases  
                • EBRT – Up to 14 fractions for spinal cord compression symptoms or single lesion or instances that require a longer fractionated course to minimize patient discomfort (e.g., nausea) (Lutz, 2017).  
                Unfavorable Risk (Poor performance status = ECOG 3 or greater or progressive metastatic disease):  
                • EBRT – Up to 5 fractions  
                Requests and supporting rationale for additional fractions can be discussed with a physician reviewer.  
                Updated:  
                2D or 3D Conformal External Beam Radiation Therapy (EBRT) is appropriate for the treatment of bone metastases  
                Good performance status = ECOG less than 3:  
                • EBRT – Up to 10 fractions for multiple bone metastases  
                Poor performance status = ECOG 3 or greater or progressive metastatic disease:  
                • EBRT – Up to 5 fractions  
                *All other treatment regimens require physician review* |

2. **TREATMENT OPTIONS REQUIRING PHYSICIAN REVIEW**

Updated:
Stereotactic Body Radiation Therapy (SBRT) for treatment of bone metastasis may be medically necessary to treat previously irradiated field. (Lutz, 2017).

SBRT is medically necessary for extracranial oligometastatic disease for an individual with One (1) to Four (4) metastatic lesions when the following criteria are met: (Cheung P, 2016; Palma 2018)
  o Good performance status: ECOG less than 3 or Karnofsky Scale greater than or equal to 70% and
  o Stable systemic disease or reasonable systemic treatment options.

3. References Added and Updated

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This guideline applies to other cancers not addressed by NIA treatment site clinical guidelines LDR (low dose rate brachytherapy) and HDR (high dose rate brachytherapy) must be requested separately and are not interchangeable.

Refer to applicable treatment site-specific guidelines for the management of primary malignancies. Applicable site-specific guidelines may include all or some of the sites below, depending on the specific program.

- Anal Cancer
- Bone Metastases
- Breast Cancer
- Cervical Cancer
- CNS Cancer
- Colon Cancer
- Rectal Cancer
- Endometrial Cancer
- Gastric Cancers
- Head and Neck Cancer
- Lung – Non-Small Cell
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- Lymphoma - Hodgkin’s Lymphoma
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- Pancreas Cancer
- Prostate Cancers

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For metastasis to the brain, regardless of primary site, refer to the NIA clinical guideline for Central Nervous System (CNS). For metastasis to bone, refer to the NIA clinical guideline for Bone Metastases. For all other metastases, refer to the NIA clinical guideline for Metastatic Disease.

**TREATMENT OPTIONS REQUIRING PHYSICIAN REVIEW**

- Brachytherapy for sites beyond those listed above may be approvable with submission of supportive documentation.¹

- Intracavitary balloon catheter brain brachytherapy for malignant gliomas or metastasis to the brain is considered *investigational*.

- Selective Internal Radiation Therapy (SIRT), also known as radioembolization with microsphere brachytherapy device (RMBD) and transarterial radioembolization, uses microscopic radioactive spheres to deliver radiation to the tumor site. Treatment is delivered through catheter injection of radioactive Yttrium-90 (90Y) microspheres into the hepatic artery. Indications for SIRT include:
  - Unresectable metastatic liver tumors – see “Metastatic Disease Guideline”
  - Unresectable metastatic liver tumors from primary colorectal cancer see “Metastatic Disease Guideline”
  - Unresectable primary hepatocellular carcinoma²
  - Unresectable neuroendocrine tumors

- **Absolute Contraindication**³
  - Fulminant liver failure (absolute)

- **Considerations/Relative Contraindications**³:
  - The tumor burden should be liver dominant, not necessarily exclusive to the liver
  - Patients should also have a performance status that will allow them to benefit from such therapy
  - A life expectancy of at least 3 months
  - Excessive tumor burden in the liver with greater than 50% to 70% of the parenchyma replaced by tumor
  - Total bilirubin greater than 2 mg/dL (in the absence of obstructive cause), which indicates severe liver function impairment. Nonobstructive bilirubin elevations may indicate that liver metastases have caused liver impairment to the degree that risks outweigh benefits for this therapy. In contrast, patients with HCC and elevated bilirubin may be treated with radioembolization if a segmental or subsegmental infusion can be performed
  - Prior radiation therapy to the liver or upper abdomen that included a significant volume of the liver
• The use of electronic brachytherapy for basal cell and squamous cell cancers of the skin (of non-melanomatous skin cancers) and benign skin conditions are considered investigational and experimental at this time.

• Coronary Artery Brachytherapy\textsuperscript{4-6}
  o Intravascular Brachytherapy for coronary arteries is medically necessary when used as an adjunct to percutaneous coronary intervention for treatment of in-stent restenosis in a native coronary artery bare-metal stent or for drug-eluting stent
  o All other uses of brachytherapy for coronary arteries are considered investigational

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INDICATIONS FOR RADIATION THERAPY AND TREATMENT OPTIONS

This guideline outlines several methods suitable for the employment of radiation therapy in conjunction with breast cancer treatment. These include the use of three-dimensional conformal radiation therapy (3D-CRT), intensity-modulated radiation therapy (IMRT), image-guided radiation therapy (IGRT) and internal radiation (brachytherapy). IMRT is not indicated as a standard treatment option for breast cancer but may be indicated for selected cases of breast cancer with close proximity to critical structures. Most external beam treatments are delivered using a high energy linear accelerator. Brachytherapy is generally delivered using temporary HDR sources such as 192-Iridium (192-Ir) or Cesium-137 (137-Cs).

Whole Breast Radiation

Three-dimensional conformal radiation therapy (3D-CRT) is the appropriate technique for treatment of the whole breast following breast conserving surgery (lumpectomy, breast conservation surgery). Electron beam or photon beam are the most commonly used techniques for delivering boost radiotherapy. Several randomized trials have confirmed the efficacy of a hypofractionated regimen in the adjuvant treatment of breast cancer.

Hypofractionated Dosage Guidelines

The use of up to 16 fractions of 3DCRT followed by a boost of 4-8 fractions for patients at higher risk of recurrence is considered medically necessary

Ultra-hypofractionated Dosage Guidelines
28.5 Gy delivered as 5 fractions, may be considered in selected patients aged >50 years following breast conservation surgery with pTis/T1/T2/N0 tumors. The optimal fractionation for the delivery of a boost is not known with this regimen

Other treatment regimens require physician review and clinical documentation that supports medical necessity.

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Partial Breast Irradiation\textsuperscript{1,4}

Accelerated partial breast irradiation (APBI) may be considered as the sole form of radiation therapy, in lieu of whole breast radiation following lumpectomy for selected cases. Patients with a small tumor, clear surgical margins after lumpectomy, and no lymph nodes containing cancer are typically eligible for APBI. APBI is considered appropriate for patients who meet all of the following criteria (Suitable Group):

- Age 50 or older
- Invasive Ductal Carcinoma or Low Grade-Intermediate Grade Ductal Carcinoma in Situ (DCIS)
- Lymph nodes negative
- No or minimal lymphovascular invasion
- Positive Estrogen Receptor
- Negative surgical margins (more than or equal to 2mm for Invasive Ductal Carcinoma, more than or equal to 3mm for DCIS)
- Tumor size less than or equal to 2cm for Invasive Ductal Carcinoma and less than or equal to 2.5cm for Ductal Carcinoma In Situ
- Clinically or microscopically unifocal
- Absence of BRCA in 1/2 mutation, if applicable

Dosage Guidelines\textsuperscript{1}
- Appropriate fractionation schemes for APBI are:
  - 30 Gy in 5 fractions once a day, preferred\textsuperscript{5,6}
  - 40 Gy in 15 fractions once a day\textsuperscript{7}
  - 34 Gy in 10 BID fractions balloon/interstitial brachytherapy\textsuperscript{8}
  - 38.5 Gy in 10 BID fractions\textsuperscript{9}

Chest Wall Radiation\textsuperscript{1}

Three-dimensional conformal radiation therapy (3D-CRT) is the appropriate technique for treatment of the chest wall following mastectomy. Chest wall scar boost may be delivered with or without bolus using electrons or photons

Dosage Guidelines
- 45-50.4 Gy up to 28 fractions with boost 59-66.4 Gy up to 37 fractions

Other Considerations

- Re-irradiation following local or regional recurrence after prior mastectomy and prior breast or chest wall radiation may be appropriate.

- For inflammatory breast cancer, whole breast or chest wall radiation, consider nodal radiation with or without chest wall boost.
Dosage Guidelines
- 45-50.4 Gy up to 28 fractions with boost 59-66.4 Gy up to 37 fractions.

*Standard radiation fractionation consists of 1.8 Gy to 2.0 Gy per day.*

TREATMENT OPTIONS REQUIRING PHYSICIAN REVIEW

Intensity modulated radiation therapy (IMRT)¹

IMRT is not indicated as a standard treatment option and should not be used routinely for the delivery of radiation therapy for breast cancer. IMRT is strictly defined by the utilization of inverse planning modulation techniques. IMRT may be appropriate for limited circumstances in which radiation therapy is indicated and 3D conformal radiation therapy (3D-CRT) techniques cannot adequately deliver the radiation prescription without exceeding normal tissue radiation tolerance, the delivery is anticipated to contribute to potential late toxicity or tumor volume dose heterogeneity is such that unacceptable hot or cold spots are created. If IMRT is utilized, techniques to account for respiratory motion should be performed.

Clinical rationale and documentation for performing IMRT rather than 2D or 3D-CRT treatment planning and delivery will need to:

- Demonstrate how 3D-CRT isodose planning cannot produce a satisfactory treatment plan (as stated above) via the use of a patient-specific dose volume histograms and isodose plans. 3D-CRT techniques such as step-and-shoot or field-in-field should be considered for the comparison.
- Confirm the IMRT requested will be inversely planned (forward plans or 'field-in-field' plans are not considered IMRT).
- Provide tissue constraints for both the target and affected critical structures.
- Upon physician review, IMRT can be approved for accelerated partial breast irradiation using 30 Gy in 5 fractions once a day regimen.⁵,⁶ Comparative 3D-CRT vs. IMRT plans are not required.

Whole Breast Irradiation (WBI)¹,²

The use of up to 16 fractions of 3DCRT followed by a boost of 4-8 fractions for patients at higher risk of recurrence is considered medically necessary. Several randomized trials have confirmed the efficacy of a hypofractionated regimen in the adjuvant treatment of breast cancer. Other treatment regimens require physician review and clinical documentation that supports medical necessity.
The use of up to 28 fractions of 3DCRT followed up with a boost of 4-8 fractions may be medically necessary if any of the following criteria are met:

- Reirradiation
- Lymph node involvement requiring treatment the supraclavicular or internal mammary nodal regions
- Concurrent chemotherapy will be administered (does not include trastuzumab or endocrine therapy)
- Collagen vascular disease
- Breast augmentation/reconstruction
- Treatment will be delivered with 3D conformal radiotherapy and the treatment plan results in dose inhomogeneity of greater than 7% in the central axis (for example, if the plan is normalized to 95%, the maximum dose is greater than 120%)

**Brachytherapy**
Interstitial brachytherapy boost treatment requires a peer review and documentation that improvement in dose delivery to the boost target cannot be delivered with external beam therapy. Other emerging techniques such as Non-invasive Image Guided Breast Brachytherapy (NIIGBB) techniques are being investigated and are not considered a medically necessary treatment option for the treatment of breast cancer.

**Proton Beam Radiation Therapy**
Proton beam is not an approved treatment option for breast cancer. There are limited clinical studies comparing proton beam therapy to 3-D conformal radiation or IMRT. Overall, studies have not shown clinical outcomes to be superior to conventional radiation therapy.

**Intraoperative radiation therapy (IORT)**
- Single Fraction Electron-beam IORT is considered medically necessary in accordance with ASTRO guidelines\(^4\) if the following criteria are met:
  - Individual is 45 years of age or older with invasive cancer
  - T Stage: Tis or T1 (tumor up to 3.5 cm)
  - Clinically node negative
  - Negative surgical margins

- The use of electronic brachytherapy for IORT (such as Intrabeam, Xoft and Papillon systems) is considered experimental, investigational, and/or unproven.

THE FOLLOWING APPLIES TO CMS (MEDICARE) MEMBERS ONLY

*For Proton Beam and Stereotactic Radiotherapy, refer to Local Coverage Determination (LCD), if applicable.*

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\(^4\)—Breast Cancer
BACKGROUND
Breast cancer is the second most commonly diagnosed cancer among women, after skin cancer, and it accounts for nearly 25% of cancer diagnoses in U.S. women. After a breast cancer diagnosis is made, it is followed by a staging evaluation to determine extent of disease (local, regional, or metastatic) and prognostic findings. Importance is placed on tumor size, lymph node involvement (sentinel node), the histo-pathological interpretation, margins of resection, and hormonal and growth-factor receptor status. Treatment for breast cancer may consist of one of several mastectomy options or breast-conserving surgery and radiation therapy.

Radiation therapy is used to treat the breast and lymph node bearing areas after partial mastectomy or lumpectomy. Since breast cancers are relatively responsive to moderate doses of radiation therapy following tumor excision, treatment for cure may be achieved by external beam techniques or by partial breast irradiation techniques.

The methods suitable for delivering breast radiation therapy have been established through clinical trials providing strong evidence in support of radiation therapy as an effective breast cancer treatment. The traditional approach utilizes tangential radiation fields to the breast and chest wall; based on the clinical and pathological factors, this may be followed by boost to the site of excision (tumor bed). The axilla and supra-clavicular regions also may be included in a separate field based on analysis of prognostic risk factors. Improvements in technology, the observation that local tumor recurrence is most frequently observed near the site of excision, and the desire to limit the extent of radiation have led to restriction of the radiation to the tumor bed (partial breast irradiation) for selected cases.

POLICY HISTORY

<table>
<thead>
<tr>
<th>Date</th>
<th>Summary</th>
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<tbody>
<tr>
<td>January 2022</td>
<td><strong>Whole Breast Radiation:</strong></td>
</tr>
<tr>
<td></td>
<td>• Added ultra-hypofractionated dosage guidelines</td>
</tr>
<tr>
<td></td>
<td><strong>Partial Breast Irradiation:</strong></td>
</tr>
<tr>
<td></td>
<td>• Updated dosage guidelines</td>
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<tr>
<td></td>
<td>• Updated criteria for indications for patients (Suitable Group):</td>
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<tr>
<td></td>
<td>o Removed No use of adjuvant chemotherapy</td>
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<tr>
<td></td>
<td>o Added Invasive Ductal Carcinoma or Low Grade-Intermediate Grade Ductal Carcinoma in Situ (DCIS)</td>
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<td></td>
<td>o Added No or minimal lymphovascular invasion</td>
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<td></td>
<td>o Added Positive Estrogen Receptor</td>
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<tr>
<td></td>
<td>o Clarified Negative surgical margins by adding “(more than or equal to 2mm for Invasive Ductal Carcinoma, more than or equal to 3mm for DCIS)”</td>
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</table>

5—Breast Cancer
Clarified tumor size (less than or equal to 2cm for Invasive Ductal Carcinoma and less than or equal to 2.5cm for Ductal Carcinoma In Situ)

**Intensity modulated radiation therapy (IMRT)**
- Added “Upon physician review, IMRT can be approved for accelerated partial breast irradiation using 30Gy in 5 fractions once a day regimen. Comparative 3D-CRT vs. IMRT plans are not required.”

**Intraoperative radiation therapy (IORT)**
- Changed to “Individual is 45 years of age or older with invasive cancer” (previously was 50 years of age or older with invasive cancer)
- Clarified TStage: Tis or T1 by adding “(tumor up to 3.5 cm)”

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### February 2021

**Whole Breast Radiation:**
Added: Several randomized trials have confirmed the efficacy of a hypofractionated regimen in the adjuvant treatment of breast cancer. Hypofractionation is preferred. Guideline changed:

**Current Guideline Deleted**
Dosage Guidelines
- 45-50.4 Gy up to 28 fractions with boost 59-66.4 Gy up to 37 fractions
- Hypofractionated radiation therapy is considered medically necessary with 40-45 Gy at 2.66 Gy per fraction in 15 to 16 fractions.

**Updated Guideline:**
Hypofractionated Dosage Guidelines

The use of up to 16 fractions of 3DCRT followed up by a boost of 4-8 fractions for patients at higher risk of recurrence is considered medically necessary

*Other treatment regimens require physician review and clinical documentation that supports medical necessity.*

**TREATMENT OPTIONS REQUIRING PHYSICIAN REVIEW:**
Added:
**Whole Breast Irradiation (WBI)** (NCCN, 2021; Smith, 2018)
The use of up to 28 fractions of 3DCRT followed by a boost of 4-8 fractions for patients at higher risk of recurrence is considered medically necessary. Several randomized trials have confirmed the efficacy of a hypo fractionated regimen in the adjuvant treatment of breast cancer. Other treatment regimens require physician review and clinical documentation that supports medical necessity.
The use of up to 28 fractions of 3DCRT followed up with a boost of 4-8 fractions may be medically necessary if any of the following criteria are met:

- Reirradiation
- Lymph node involvement requiring treatment the supraclavicular or internal mammary nodal regions.
- Concurrent chemotherapy will be administered (does not include trastuzumab or endocrine therapy)
- Collagen vascular disease
- Breast augmentation/reconstruction
- Treatment will be delivered with 3D conformal radiotherapy and the treatment plan results in dose inhomogeneity of greater than 7% in the central axis (for example, if the plan is normalized to 95%, the maximum dose is greater than 120%)

<table>
<thead>
<tr>
<th>Added and updated references</th>
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<tr>
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</table>
REFERENCES


ADDITIONAL RESOURCES


Reviewed / Approved by NIA Clinical Guideline Committee
GENERAL INFORMATION
It is an expectation that all patients receive care/services from a licensed clinician. All appropriate supporting documentation, including recent pertinent office visit notes, laboratory data, and results of any special testing must be provided. If applicable: All prior relevant imaging results and the reason that alternative imaging cannot be performed must be included in the documentation submitted.

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INDICATIONS FOR RADIATION THERAPY AND TREATMENT OPTIONS

Definitive/Preoperative Radiation Therapy¹
- Stage IA –IA2– Brachytherapy (LDR or HDR) +/- 2D/3D-CRT (40-50 Gy; 28 fx max)
- Stage IB1 – Pelvic 2D/3D-CRT (40-50 Gy; 28 fx max) + brachytherapy boost
- Stage IB2-IIA – Pelvic radiation therapy 2D/3D-CRT (40-50 Gy; 28 fx max) + brachytherapy boost) and concomitant chemotherapy +/- adjuvant hysterectomy
- Stage IIB-IVA – Pelvic and/or paraortic 2D/3D-CRT + brachytherapy + concurrent chemotherapy.
- Stage IVB – 2D/3D-CRT +/- brachytherapy for palliation only (symptom control)

"Grossly involved unresected nodes may be evaluated for boosting with an additional 10-15Gy"

Post-operative (Adjuvant) Radiation Therapy¹
- Patients found to have deep cervical stromal invasion, lymphovascular invasion and/or bulky primary tumors.
  - Pelvic 2D/3D-CRT/IMRT (45-50Gy; 28 fx max) +/- concurrent chemotherapy
- Patients with positive nodes, positive margins and/or parametrial invasion –
  - Pelvic 2D/3D-CRT/IMRT (45-50Gy; 28 fx max) + concurrent chemotherapy
  - Pelvic 2D/3D-CRT/IMRT (45-50Gy; 28 fx max) +/- vaginal brachytherapy boost (LDR or HDR) can be considered in women with a positive margin.
- "Grossly involved unresected nodes may be evaluated for boosting with an additional 10-15Gy."
- "Unless otherwise indicated, standard radiation fractionation consists of 1.8 GY to 2.0 GY per day."

Local /Regional Recurrence¹
- No previous RT or outside previous RT fields
  - 2D/3D-CRT + chemotherapy +/- brachytherapy
- Previous RT
  - Intraoperative Radiation Therapy (IORT) for centralized disease

¹ National Imaging Associates, Inc. (NIA) is a subsidiary of Evolent Health LLC.

TREATMENT OPTIONS REQUIRING ADDITIONAL CLINICAL REVIEW¹:

Intensity modulated radiation therapy (IMRT)
IMRT is not indicated as a standard treatment option and should not be used routinely for the delivery of radiation therapy for cervical cancer. IMRT is strictly defined by the utilization of inverse planning modulation techniques. IMRT may be appropriate for circumstances in which radiation therapy is indicated and

- Non-IMRT techniques cannot adequately deliver the radiation prescription without exceeding normal tissue radiation tolerance. The non-IMRT delivery is anticipated to contribute to potential late toxicity
- Tumor volume dose heterogeneity from non-IMRT techniques is such that unacceptable hot or cold spots are created

Requests for IMRT treatment delivery to the cervix will be reviewed for medical necessity prior to authorization based on the above criteria. Clinical rationale and documentation for performing IMRT rather than non-IMRT techniques must be provided for review. This includes a statement of medical necessity from the requesting provider and a dosimetric comparison plan addressing the approval criteria above.

The plan will:
- Demonstrate how non-IMRT treatment planning cannot produce a satisfactory treatment plan (as stated above) via the use of patient-specific dose volume histograms and isodose plans.
- Provide tissue constraints for both the target and affected critical structures.

IMRT for Post-operative Radiation
IMRT for post-operative radiation therapy is approvable. If there is gross residual disease and the area(s) can be sufficiently utilized, a boost can be added to a total dose of 60-70Gy, respecting normal tissue sensitivity. For gross nodal disease, consider boost to 60-65Gy while respecting normal tissue constraints.¹⁻³


SBRT is an approach that allows for delivery of very high doses of focused EBRT in 1-5 fractions and may be applied to isolated metastatic sites, considering can be given for limited disease in the re-irradiation setting.⁴⁻⁵
Proton Beam Radiation Therapy
Proton beam is not an approved treatment option for cervical cancer. Proton beam has not been proven superior treatment to conventional radiation therapy.

THE FOLLOWING APPLIES TO CMS (MEDICARE) MEMBERS ONLY:

For Proton Beam and Stereotactic Radiotherapy, refer to Local Coverage Determination (LCD), if applicable.

BACKGROUND
The role of radiation therapy in the treatment of cervical cancer has been long established through clinical trial, providing strong evidence of support as an effective cervical cancer treatment. The traditional approach utilizes external beam irradiation therapy to the pelvis ± periaortic lymph nodes, as well as some form of brachytherapy boost, based on clinical and pathologic factors. There have been improvements in radiation therapy technology, reducing dose to normal surrounding tissue (bladder, rectum, and small bowel), but the majority of the experience to date is based on a point A dosing system.

This guideline outlines several methods suitable for the employment of radiation therapy in conjunction with cervical cancer treatment. These include the use of three-dimensional conformal radiation therapy (3D-CRT), intensity-modulated radiation therapy (IMRT), image-guided radiation therapy (IGRT), and internal radiation (brachytherapy). Although intensity-modulated radiation therapy (IMRT) is becoming more widely available, the routine use in treating cervical cancer remains to be validated. IMRT may be useful when high doses are required to treat gross disease in regional lymph nodes. However, IMRT should not be used as routine alternatives to brachytherapy for treatment of central disease in patients with an intact cervix. Although there have been significant advances in imaging, planning, and treatment delivery, this must be tailored to a thorough understanding to the stage of disease, pathways for dissemination and recurrence risk. Most external beam treatments are delivered using a high-energy linear accelerator. Brachytherapy is generally delivered as either low dose permanent implant or high dose rate implant. Principles of radiation therapy for these guidelines closely follow what is recommended both by the American Brachytherapy Society (Cervical Cancer Brachytherapy Task Group), as well as in National Comprehensive Cancer Network Practice Guidelines for Cervical Cancer.

POLICY HISTORY:

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<thead>
<tr>
<th>Date</th>
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<td>• Added IMRT to Postoperative (Adjuvant) Radiation Therapy</td>
</tr>
<tr>
<td></td>
<td>• Moved the following from Local/Regional Recurrence section to Postoperative (Adjuvant) Radiation Therapy section</td>
</tr>
<tr>
<td></td>
<td>o Grossly involved unresected nodes may be evaluated for boosting with an additional 10-15Gy</td>
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</table>
• Unless otherwise indicated, standard radiation fractionation consists of 1.8 Gy to 2.0 Gy per day

- Under Treatment Options Requiring Additional Clinical Review:
  - Added IMRT for Post-operation Radiation
  - Clarified that SBRT can be given for limited disease in the re-irradiation setting

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<th>Changes</th>
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<tbody>
<tr>
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<td>February 2020</td>
<td>Updated references</td>
</tr>
<tr>
<td>February 2019</td>
<td>Added and updated references</td>
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</table>
REFERENCES


ADDITIONAL RESOURCES


Reviewed / Approved by NIA Clinical Guideline Committee
GENERAL INFORMATION
It is an expectation that all patients receive care/services from a licensed clinician. All appropriate supporting documentation, including recent pertinent office visit notes, laboratory data, and results of any special testing must be provided. If applicable: All prior relevant imaging results and the reason that alternative imaging cannot be performed must be included in the documentation submitted.

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## INDICATIONS FOR RADIATION THERAPY FOR PATIENTS WITH METASTATIC CENTRAL NERVOUS SYSTEM TUMORS

### Metastatic Brain Tumors

- Whole Brain Radiation Therapy (WBRT) with 2D or 3D Conformal treatment is appropriate for treatment Metastatic Brain Tumors - Up to 15 Fractions

- Stereotactic Radiosurgery/Stereotactic Body Radiotherapy (SRS/SBRT) up to 5 fractions is medically necessary if all the following criteria are met:
  - Treatment for lesions ≤4cm,
  - Controlled systemic disease or reasonable systemic treatment options
  - Eastern Cooperative Oncology Group (ECOG) rating of less than 3,
  - 4 or less metastasis prior to procedure

- Intensity Modulated Radiation Therapy requires physician review

### Post Metastasis Resection

- WBRT 20-40 Gy (20 fractions maximum)
- WBRT + external beam boost
- Stereotactic Radiosurgery/Stereotactic Body Radiotherapy (SRS/SBRT) post metastasis resection (up to 5 fractions)

### Metastatic Spine Tumors

- 2D/3D-CRT – 8-30Gy (maximum 10 fractions)
- Dose/fraction dependent on tumor type and performance status
- Stereotactic radiotherapy/IMRT may be appropriate for re-treatment.
INDICATIONS FOR PROTON BEAM THERAPY

Treatment of the following in children less than 21 years of age:

- Metastatic central nervous system tumors when sparing of surrounding normal tissues cannot be achieved with photon therapy

Treatment at any age:

- Spinal tumors (primary or metastatic) where spinal cord has previously been treated with radiation or where the spinal cord tolerance may be exceeded with conventional treatment
- Tumors at the base of skull (chordoma, chondrosarcomas)

Requests for Proton Beam Radiation Therapy beyond the indications listed above require physician review by a radiation oncologist as outlined below to determine medical necessity.

TREATMENT OPTIONS REQUIRING PHYSICIAN REVIEW

Intensity Modulated Radiation Therapy (IMRT)\(^1\)

Intensity Modulated Radiation Therapy (IMRT) may be appropriate for limited circumstances in which radiation therapy is indicated and 3D conformal radiation therapy (3D-CRT) techniques cannot adequately deliver the radiation prescription without exceeding normal tissue radiation tolerance, the delivery is anticipated to contribute to potential late toxicity or tumor volume dose heterogeneity is such that unacceptable hot or cold spots are created.

Clinical rationale and documentation for performing IMRT rather than 2D or 3D-CRT treatment planning and delivery will need to:

- Demonstrate how 3D-CRT isodose planning cannot produce a satisfactory treatment plan (as stated above) via the use of patient-specific dose volume histograms and isodose plans.
- Provide tissue constraints for both the target and affected critical structures.

Hippocampal Sparing Whole Brain Intensity Modulated Radiation Therapy\(^1-4\)

- Hippocampal sparing whole brain IMRT is considered medically necessary for metastatic brain lesions in individuals with all of the following:
  - Good performance status: ECOG rating is less than 3
  - Who have a prognosis of at least 4 months
  - No metastases within 5mm of the hippocampi
  - Have not had prior WBRT or external beam radiation to the brain
  - Do not have leptomeningeal disease
  - Whose primary histology is not germ cell, small cell, lymphoma or unknown
• Dosage Guidelines
  o Standard doses vary between 20Gy and 37.5Gy in 5-15 fractions. Hippocampal avoidance with WBRT (HA-WBRT) (plus memantine) 30Gy in 10 fractions is preferred for patients with a better prognosis. For patients with poor predicted prognosis and with symptomatic brain metastases, standard WBRT of 20Gy in 5 fractions is a reasonable option.

Stereotactic Radiosurgery (SRS) or Stereotactic Body Radiation Therapy (SBRT)¹
If SRS or SBRT is not indicated as a medically necessary treatment option, a peer review will be required. For patients with 4 lesions or more, SRS may be appropriate in patients with good performance status and low overall tumor volume.

Proton Beam Radiation Therapy

• Proton Beam Radiation Therapy for central nervous system lesions adjacent to the brain stem, spinal cord, or optic nerve requires physician review by a radiation oncologist. A treatment plan with a comparison to conventional IMRT/SRS may be required.
• Requests for Proton Beam Radiation Therapy beyond the indications listed above require physician review by a radiation oncologist.

BACKGROUND
Metastatic tumors for the Central Nervous System (CNS) start in other organs, e.g., lung, breast, or colon, and spread to the brain and spinal cord. In adults, these are more common than primary CNS/brain tumors. Both primary and metastatic brain tumors can readily spread through the brain or spinal cord, destroying and compressing normal brain tissue. Metastatic brain tumors occur at some point in 20 to 40% of persons with cancer and are the most common type of brain tumor. Prognosis is dependent on several factors including the type of tumor, location, response to treatment, an individual's age, and overall health status.

Surgery, radiation therapy and chemotherapy are the primary modalities used to treat CNS tumors, either alone or in combination. There are many different approaches in delivering radiation therapy to CNS tumors, including fractionated radiation therapy, stereotactic fractionated radiotherapy, stereotactic radiosurgery, brachytherapy, and proton beam irradiation. Fractionated conformal beam irradiation is the most common approach.

Radiation therapy may be delivered following surgical resection, debulking or biopsy procedures. It may also be used to treat recurrences in patients whose initial treatment was surgery alone. The value of radiation therapy lies in its ability to cure some patients and to prolong disease-free survival for others. Combined modality approaches that include chemotherapy may also contribute to prolonged disease-free survival in pediatric patients with medulloblastoma, germ cell tumors and gliomas.
The dose and fractionation of radiation depends not only on the tumor type, but also in the curative/palliative setting.

**POLICY HISTORY**

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<tr>
<td>January 2022</td>
<td>• Under Hippocampal Sparing Whole Brain Intensity Modulated Radiation Therapy:&lt;br&gt;  o Clarified that IMRT is considered medically necessary for metastatic brain lesions in individuals with all of the following:&lt;br&gt;  ▪ Good performance status: ECOG rating is less than 3&lt;br&gt;  ▪ Who have a prognosis of at least 4 months&lt;br&gt;  ▪ No metastases within 5mm of the hippocampi&lt;br&gt;  ▪ Have not had prior WBRT or external beam radiation to the brain&lt;br&gt;  ▪ Do not have leptomeningeal disease&lt;br&gt;  ▪ Whose primary histology is not germ cell, small cell, lymphoma or unknown&lt;br&gt;  o Added Dosage Guidelines</td>
</tr>
<tr>
<td>February 2021</td>
<td>Metastatic Brain Tumors (NCCN, 2018)&lt;br&gt;Deleted&lt;br&gt;• Favorable Risk (stable systemic disease or new diagnosis, pathologically confirmed diagnosis, no resection)&lt;br&gt;  o Whole Brain Radiation Therapy (WBRT) 2D/3D-CRT – 20-40 Gy (maximum 20 fractions)&lt;br&gt;  o WBRT 2D/3D-CRT + 3D/IMRT boost&lt;br&gt;  o Stereotactic Radiosurgery/Stereotactic Body Radiotherapy (SRS/SBRT) alone for lesions ≤4cm, controlled systemic disease, Eastern Cooperative Oncology Group (ECOG) rating of less than 3, 4 or less metastasis prior to procedure (maximum 5 fractions)&lt;br&gt;• Unfavorable Risk (poor systemic control, no role for chemotherapy, pathologically confirmed diagnosis, no resection)&lt;br&gt;  o WBRT 2D/3D-CRT – 20-40 Gy (maximum 20 fractions)&lt;br&gt;• For metastatic brain tumors with unfavorable risk (poor systemic control, no role for chemotherapy, pathologically confirmed diagnosis, no resection), the following requests require review with a physician reviewer:&lt;br&gt;  o WBRT 2D/3D-CRT + SRS/SBRT boost (15-24 Gy, maximum 1 fractions)&lt;br&gt;  o WBRT 2D/3D-CRT + fractionated SRS/SBRT boost (up to 5 fractions and limited to symptomatic metastasis not responding to WBRT)</td>
</tr>
</tbody>
</table>
• Whole Brain Radiation Therapy (WBRT) with 2D or 3D Conformal treatment is appropriate for treatment Metastatic Brain Tumors - Up to 15 Fractions

• Stereotactic Radiosurgery/Stereotactic Body Radiotherapy (SRS/SBRT) up to 5 fractions is medically necessary if all the following criteria are met:
  • Treatment for lesions ≤4cm,
  • controlled systemic disease or reasonable systemic treatment options
  • Eastern Cooperative Oncology Group (ECOG) rating of less than 3,
  • 4 or less metastasis prior to procedure

• Intensity Modulated Radiation Therapy requires physician review

TREATMENT OPTIONS REQUIRING PHYSICIAN REVIEW:
Added:
Hippocampal Sparing Whole Brain Intensity Modulated Radiation Therapy (Brown RD,2020; NCCN, 2019)
Hippocampal sparing whole brain IMRT is considered medically necessary for metastatic brain lesions in individuals with:
  • Good performance status: ECOG rating is less than 3 and
  • Previously irradiated field or
3DCRT cannot be safely delivered without exceeding normal tissue tolerance.

Updated:
Stereotactic Radiosurgery (SRS) or Stereotactic Body Radiation Therapy (SBRT) (NCCN, 2018)
If SRS or SBRT is not indicated as a medically necessary treatment option, a peer review will be required. For patients with 4 lesions or more SRS may be appropriate in patients with good performance status and low overall tumor volume.”

Added References
February 2020   Updated references
February 2019   Added and updated references
REFERENCES


ADDITIONAL RESOURCES


23. Varlotto JM, Flickinger JC, Niranjan A, Bhatnagar A, Kondziolka D, Lunsford LD. The impact of whole-brain radiation therapy on the long-term control and morbidity of patients surviving more than...

Reviewed / Approved by NIA Clinical Guideline Committee
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INDICATIONS FOR RADIATION THERAPY FOR PRIMARY CNS NEOPLASMS

Gliomas¹

- Low Grade Tumors – Grade I or II
  - Post-operative/biopsy – 3D-CRT/IMRT (max 33 fx)
- Recurrence – Low Grade
  - 3D-CRT/IMRT – (max 33 fx)
  - Consider reirradiation on select cases. Dose on individual basis
- High Grade Tumors – Grade III or IV
  - Post-operative/biopsy – 3D-CRT/IMRT (max 33 fx)
- Recurrence – High Grade
  - 3D-CRT/IMRT – (max 33 fx)
  - Consider reirradiation on select cases. Dose on individual basis.

Ependymoma – High (Anaplastic) or Low Grade¹

- Brain and/or spine 3D-CRT/IMRT (max 33 fx)

Meningiomas¹

- Low Grade and High Grade
  - 3D-CRT/IMRT (max 33 fx)
  - SRS/SBRT (max 5 fx)

CNS Lymphoma¹

- Complete response to chemotherapy – 3D-CRT (max 20 fx)
- Less than complete response to chemotherapy
- Whole Brain – 3D-CRT (max 20 fx) with or without Limited field boost – 3D-CRT/IMRT (max 25 fx)

* National Imaging Associates, Inc. (NIA) is a subsidiary of Evolent Health LLC.

¹—CNS – Primary – RadOnc
Medulloblastoma/Supratentorial PNET (Adult)^1

Craniospinal radiation with brain primary site boost – 3D-CRT/IMRT (max 31 fx total)

Primary Spinal Cord^1

- 3D-CRT/IMRT (max 28 fx)
  - Tumor below conus medullaris 3D-CRT/IMRT (max 33 fx)
- SRS/SBRT – (max 5 fx)

INDICATIONS FOR RADIATION THERAPY FOR PATIENTS WITH METASTATIC CENTRAL NERVOUS SYSTEM TUMORS

Metastatic Brain Tumors^1

- Whole Brain Radiation Therapy (WBRT) with 2D or 3D Conformal treatment is appropriate for treatment Metastatic Brain Tumors - Up to 15 Fractions
- Stereotactic Radiosurgery/Stereotactic Body Radiotherapy (SRS/SBRT) up to 5 fractions is medically necessary if all the following criteria are met:
  - Treatment for lesions ≤4cm
  - Controlled systemic disease or reasonable systemic treatment options
  - Eastern Cooperative Oncology Group (ECOG) rating of less than 3
  - 4 or less metastasis prior to procedure
- Intensity Modulated Radiation Therapy requires physician review

Post Metastasis Resection^1

- WBRT 20-40 Gy (20 fractions maximum)
- WBRT + external beam boost
- Stereotactic Radiosurgery/Stereotactic Body Radiotherapy (SRS/SBRT) post metastasis resection (up to 5 fractions)

Metastatic Spine Tumors^1

- 2D/3D-CRT – 8-30 Gy (maximum 10 fractions)
- Dose/fraction dependent on tumor type and performance status
- Stereotactic radiotherapy/IMRT may be appropriate for re-treatment.
INDICATIONS FOR PROTON BEAM THERAPY

Treatment of the following in children less than 21 years of age:

- Primary, metastatic, or benign solid tumors when sparing of surrounding normal tissues cannot be achieved with photon therapy

Treatment at any age:

- Spinal tumors (primary or metastatic) where spinal cord has previously been treated with radiation or where the spinal cord tolerance may be exceeded with conventional treatment
- Tumors at the base of skull (chordoma, chondrosarcoma)
- Malignant and benign primary CNS tumors: Consider proton therapy for patients with good long-term prognosis (grade 3 IDH-mutant tumors\(^2\) and 1p19q codeleted tumors\(^3\)) to better spare uninvolved brain and preserve cognitive function
- Craniospinal RT: To reduce toxicity from CSI in adults, consider the use of IMRT or protons if available (for patients with positive CSF or known metastatic disease)\(^4\)

Requests for Proton Beam Radiation Therapy beyond the indications listed above require physician review by a radiation oncologist as outlined below to determine medical necessity.

TREATMENT OPTIONS REQUIRING ADDITIONAL CLINICAL REVIEW

Intensity modulated radiation therapy (IMRT)

If IMRT is not indicated as a standard treatment option, a peer review will be indicated. IMRT may be appropriate for limited circumstances in which radiation therapy is indicated and 3D conformal radiation therapy (3D-CRT) techniques cannot adequately deliver the radiation prescription without exceeding normal tissue radiation tolerance, the delivery is anticipated to contribute to potential late toxicity, or tumor volume dose heterogeneity is such that unacceptable hot or cold spots are created.

Clinical rationale and documentation for performing IMRT rather than 2D or 3D-CRT treatment planning and delivery will need to:

- Demonstrate how 3D-CRT isodose planning cannot produce a satisfactory treatment plan (as stated above) via the use of patient-specific dose volume histograms and isodose plans.
- Provide tissue constraints for both the target and affected critical structures

Hippocampal Sparing Whole Brain Intensity Modulated Radiation Therapy\(^1, 5-7\)

- Hippocampal sparing whole brain IMRT is considered medically necessary for metastatic brain lesions in individuals with all of the following:
  - Good performance status: ECOG rating is less than 3
  - Who have a prognosis of at least 4 months
• No metastases within 5mm of the hippocami
• Have not had prior WBRT or external beam radiation to the brain
• Do not have leptomeningeal disease
• Whose primary histology is not germ cell, small cell, lymphoma or unknown

• Dosage Guidelines
  o Standard doses vary between 20Gy and 37.5Gy in 5-15 fractions. Hippocampal avoidance with WBRT (HA-WBRT) (plus memantine) 30Gy in 10 fractions is preferred for patients with a better prognosis. For patients with poor predicted prognosis and with symptomatic brain metastases, standard WBRT of 20Gy in 5 fractions is a reasonable option.

Stereotactic Radiosurgery (SRS) or Stereotactic Body Radiation Therapy (SBRT)¹
  • If SRS or SBRT is not indicated as a medically necessary treatment option, a peer review will be required. For patients with 4 lesions or more, SRS may be appropriate in patients with good performance status and low overall tumor volume.

Proton Beam Radiation Therapy
  • Requests for Proton Beam Radiation Therapy require a peer review with a radiation oncologist. A treatment plan with a comparison to conventional IMRT/SRS may be required. See Proton Beam Guideline.

BACKGROUND
There are many different types of brain tumors. Because brain tumors are located at the control center for thought, emotion, and movement, their effects on an individual's physical and cognitive abilities can be devastating. Prognosis or expected outcome is dependent on several factors including the type of tumor, location, response to treatment, an individual's age, and overall health status. The most common CNS tumors are astrocytomas and glioblastomas, followed by meningiomas and a variety of other less common tumors. Metastatic brain tumors start in other organs, e.g., lung, breast, or colon and spread to the brain. In adults, these are more common than primary brain tumors. Both primary and metastatic brain tumors can readily spread through the brain or spinal cord, destroying and compressing normal brain tissue.

Surgery, radiation therapy and chemotherapy are the primary modalities used to treat CNS tumors, either alone or in combination. The first step in brain tumor treatment is usually surgical resection, with two primary goals: (1) removing as much of the tumor as possible while preserving neurological function and (2) establishing a histologic diagnosis. If the tumor cannot be completely removed, subtotal resection, (debulking) can increase the effectiveness of other treatments. Deep-seated tumors of the brain stem, e.g., pontine gliomas, are generally diagnosed and treated based on clinical and imaging evidence.
## POLICY HISTORY

<table>
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<th>Date</th>
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| January 2022 | • Under Indications for Proton Beam Therapy (Treatment at any age)  
  o Added: Malignant and benign primary CNS tumors, consider for patients with good long-term prognosis (grade 3 IDH-mutant tumors and 1p19q co-deleted tumors)  
  o Added: craniospinal RT to reduce toxicity from CSI in adults, consider use of IMRT or protons if available (for patients with positive CSF or known metastatic disease)  
  • Under Hippocampal Sparing Whole Brain Intensity Modulated Radiation Therapy, added that all of the following must be met:  
  o Good performance status: ECOG rating is less than 3  
  o Who have a prognosis of at least 4 months  
  o No metastases within 5mm of the hippocampi  
  o Have not had prior WBRT or external beam radiation to the brain  
  o Do not have leptomeningeal disease  
  o Whose primary histology is not germ cell, small cell, lymphoma or unknown  
  • Added: Dosage Guidelines under Hippocampal Sparing Whole Brain Intensity Modulated Radiation Therapy |
| February 2021 | Deleted: Metastatic Brain Tumors (NCCN, 2018)  
  • Favorable Risk (stable systemic disease or new diagnosis, pathologically confirmed diagnosis, no resection)  
  o Whole Brain Radiation Therapy (WBRT) 2D/3D-CRT – 20-40 Gy (maximum 20 fractions)  
  o WBRT 2D/3D-CRT + 3D/IMRT boost  
  o Stereotactic Radiosurgery/Stereotactic Body Radiotherapy (SRS/SBRT) alone for lesions ≤4cm, controlled systemic disease, Eastern Cooperative Oncology Group (ECOG) rating of less than 3, 4 or less metastasis prior to procedure (maximum 5 fractions)  
  • Unfavorable Risk (poor systemic control, no role for chemotherapy, pathologically confirmed diagnosis, no resection)  
  o WBRT 2D/3D-CRT – 20-40 Gy (maximum 20 fractions)  
  • Whole Brain Radiation Therapy (WBRT) with 2D or 3D Conformal treatment is appropriate for treatment Metastatic Brain Tumors - Up to 20 Fractions  
  Updated: Metastatic Brain Tumors (NCCN, 2018)  
  • Whole Brain Radiation Therapy (WBRT) with 2D or 3D Conformal treatment is appropriate for treatment Metastatic Brain Tumors - Up to 15 Fractions |
- Stereotactic Radiosurgery/Stereotactic Body Radiotherapy (SRS/SBRT) up to 5 fractions is medically necessary if all the following criteria are met:
  - Treatment for lesions ≤4 cm,
  - Controlled systemic disease or reasonable systemic treatment options
  - Eastern Cooperative Oncology Group (ECOG) rating of less than 3,
  - 4 or less metastasis prior to procedure

- Intensity Modulated Radiation Therapy requires physician review

**TREATMENT OPTIONS REQUIRING ADDITIONAL CLINICAL REVIEW**

Added: Hippocampal Sparing Whole Brain Intensity Modulated Radiation Therapy (Brown RD, 2020; NCCN, 2019)

Hippocampal sparing whole brain IMRT is considered medically necessary for metastatic brain lesions in individuals with:
- Good performance status: ECOG rating is less than 3 and
- Previously irradiated field or
- 3DCRT cannot be safely delivered without exceeding normal tissue tolerance.

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<th>February 2020</th>
<th>Updated references</th>
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<tr>
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<td>Added and updated references</td>
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REFERENCES


ADDITIONAL RESOURCES


https://www.cancer.net/cancer-types/brain-tumor/statistics


Reviewed / Approved by NIA Clinical Guideline Committee
GENERAL INFORMATION

It is an expectation that all patients receive care/services from a licensed clinician. All appropriate supporting documentation, including recent pertinent office visit notes, laboratory data, and results of any special testing must be provided. If applicable: All prior relevant imaging results and the reason that alternative imaging cannot be performed must be included in the documentation submitted.

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INDICATIONS FOR RADIATION THERAPY

- Colon Cancer
  - Radiation therapy is indicated for T4 tumors with penetration/perforation, intermediate/positive margins or for palliative care to relieve symptoms for Stage IV metastatic disease. Radiation therapy should not replace surgical resection.
    - 3D Conformal is recommended. 45-50Gy in 25-28 fractions. Boost dose for positive margins an option.\(^1\)
    - IORT, if available, should be considered for very close or positive margins following resection, particularly for T4 or recurrent cancers, as an additional boost.\(^1\) Where IORT is not available, 10-20Gy external beam radiation and/or brachytherapy to a limited volume can be considered soon after surgery but prior to adjuvant chemotherapy.
    - IMRT is not indicated as a standard treatment option and should be reserved for unique situations but may be utilized for re-irradiation of previously treated patients with recurrence.\(^1\) (Requires Physician Review)

- Proton beam is not an approved treatment option for colorectal cancer.

- Rectal Cancer
  - Radiation therapy is considered a medically necessary for the following clinical indications: Preoperative or postoperative/adjuvant therapy or as primary therapy if tumor inoperable. Radiation therapy should not replace surgical resection.\(^2\)
    - 3D Conformal Radiation Therapy recommended. 45 -54Gy delivered 25 -30 fractions at 1.8 -2.0Gy per fraction. Boost may be an option. Dosage exceeding 54Gy may be necessary for un-resectable tumors.\(^2\)
- IORT, if available, should be considered for very close or positive margins following resection, particularly for T4 or recurrent cancers, as an additional boost. Where IORT is not available, 10-20Gy external beam radiation and/or brachytherapy to a limited volume can be considered soon after surgery but prior to adjuvant chemotherapy.²

- IMRT is not indicated as a standard treatment option and should be reserved for unique situations but may be utilized for re-irradiation of previously treated patients with recurrence.² (Requires Physician review)

- Proton beam is not an approved treatment option for colorectal cancer.

### TREATMENT OPTIONS REQUIRING PHYSICIAN REVIEW

**Intensity Modulated Radiation Therapy (IMRT)**

IMRT is not indicated as a standard treatment option and should not be used routinely for the delivery of radiation therapy for colorectal cancer. IMRT may be appropriate for limited circumstances in which radiation therapy is indicated and 3D conformal radiation therapy (3D-CRT) techniques cannot adequately deliver the radiation prescription without exceeding normal tissue radiation tolerance, the delivery is anticipated to contribute to potential late toxicity or tumor volume dose heterogeneity is such that unacceptable hot or cold spots are created.

Clinical rationale and documentation for performing IMRT rather than 2D or 3D-CRT treatment planning and delivery will need to:

- Demonstrate how 3D-CRT isodose planning cannot produce a satisfactory treatment plan (as stated above) via the use of a patient-specific dose volume histograms and isodose plans.

- Provide tissue constraints for both the target and affected critical structures.

IMRT can be approved for low-lying rectal cancers requiring treatment of inguinal lymph nodes. These tumors are often treated like anal cancer. No comparative plan would be necessary.

**Proton Beam Radiation Therapy**

Proton beam is not an approved treatment option for colorectal cancer. There are limited clinical studies comparing proton beam therapy to 3-D conformal radiation. Overall, studies have not shown clinical outcomes to be superior to conventional radiation therapy.

**Stereotactic Radiation Therapy**

SBRT is not a routine treatment option for Colon cancer but may be considered for patients with oligometastatic disease or for tumors in or near previously irradiated regions.
THE FOLLOWING APPLIES TO CMS (MEDICARE) MEMBERS ONLY

For Proton Beam and Stereotactic Radiotherapy refer to Local Coverage Determination (LCD), if applicable

BACKGROUND
Colorectal cancer, also called colon cancer or large bowel cancer, includes cancerous growths in the colon, rectum and appendix. Cancer of the colon is generally treated with both surgery and chemotherapy. Surgery may be used in the treatment of all stages of rectal cancer. Preoperative radiation therapy and chemotherapy (neoadjuvant therapy) are given to shrink the tumor before surgery, resulting in improved probability for successful resection. Postoperative radiation therapy and chemotherapy (adjuvant therapy) may decrease local recurrence and improve overall survival. It may also be used for palliative treatment to relieve symptoms of metastatic disease. In addition, local recurrences that cause pain, bleeding or other symptoms are appropriately treated with radiation therapy.

POLICY HISTORY

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</tbody>
</table>
| February 2021| • Added: SBRT is not a routine treatment option for Colon cancer but may be considered for patients with oligometastatic disease or for tumors in or near previously irradiated regions.  
• Updated references |
| February 2020| • No changes                                                             |
| February 2019| • Removed section: ‘Pediatric Considerations’ for consistency with other GLs  
• Added and updated references |
REFERENCES


ADDITIONAL RESOURCES


Reviewed / Approved by NIA Clinical Guideline Committee
GENERAL INFORMATION
It is an expectation that all patients receive care/services from a licensed clinician. All appropriate supporting documentation, including recent pertinent office visit notes, laboratory data, and results of any special testing must be provided. If applicable: All prior relevant imaging results and the reason that alternative imaging cannot be performed must be included in the documentation submitted.

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INDICATIONS FOR RADIATION THERAPY AND TREATMENT OPTIONS

**Post-operative**
- Brachytherapy Only (HDR or LDR, 5 fx maximum)
  - Stage IA – with adverse risk factors
  - Stage IA – without risk factors (Grades G2, 3)
  - Stage IB
  - Stage II – (Grade G1)
- External Beam Radiation Therapy Only (2D, 3D-CRT, 45-50.4 Gy, 28 fx maximum)
  - Stage IA – with adverse risk factors (Grades G2, 3)
  - Stage IB – without adverse risk factors (Grade G3)
  - Stage IB – with risk factors
  - Stage II – (Grade G1)
  - Stage III
  - Stage IV
- External Beam (2D, 3D-CRT, 45-50.4Gy, 28 fx maximum) and Brachytherapy (HDR or LDR, 5 fx maximum)
  - Stage IA – with adverse risk factors (Grades G2, 3)
  - Stage IB – without risk factors (Grade G3)
  - Stage IB – with risk factors
  - Stage II – (Grades G1, 2, 3)
  - Stage IIIA & IIIB & IIIC (Grades G1, 2, 3)

**Medically Inoperable/ Pre-Operative**
- Brachytherapy Only (HDR or LDR, 7 fx maximum)
  - Stage I & II

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* National Imaging Associates, Inc. (NIA) is a subsidiary of Evolent Health LLC.
- **External Beam Radiation Therapy Only (2D, 3D-CRT, 45-50 Gy, 28 fx maximum)**
  - All Stages
- **External Beam (2D, 3D-CRT, 45-50.4 Gy) and Brachytherapy (HDR or LDR, 4 fx maximum)**
  - All Stages

**Palliative**
- Up to 10 fx

*Unless otherwise indicated, standard radiation fractionation consists of 1.8 Gy to 2.0 Gy per day.*

**TREATMENT OPTIONS REQUIRING ADDITIONAL CLINICAL REVIEW**

**Intensity Modulated Radiation Therapy (IMRT)**

IMRT is not indicated as a standard treatment option and should not be used routinely for the delivery of radiation therapy for endometrial cancer. IMRT is strictly defined by the utilization of inverse planning modulation techniques. IMRT may be appropriate for limited circumstances in which radiation therapy is indicated and 3D conformal radiation therapy (3D-CRT) techniques cannot adequately deliver the radiation prescription without exceeding normal tissue radiation tolerance, the delivery is anticipated to contribute to potential late toxicity or tumor volume dose heterogeneity is such that unacceptable hot or cold spots are created.

Clinical rationale and documentation for performing IMRT rather than 2D or 3D-CRT treatment planning and delivery will need to:

- Demonstrate how 3D-CRT isodose planning cannot produce a satisfactory treatment plan (as stated above) via the use of a patient-specific dose volume histograms and isodose plans.

- Provide tissue constraints for both the target and affected critical structures.

**Post-Operative IMRT**

IMRT for post-operative radiation therapy is approvable. If there is gross residual disease and the area(s) can be sufficiently utilized, a boost can be added to a total dose of 60-70Gy, respecting normal tissue sensitivity. For gross nodal disease, consider boost to 60-65Gy while respecting normal tissue constraints.

**Stereotactic Body Radiation Therapy (SBRT)**

Stereotactic Body Radiation Therapy is not a standard treatment option for the treatment of endometrial cancer.

**Proton Beam Radiation Therapy**

Proton beam is not an approved treatment option for endometrial cancer. Proton beam has not been proven superior treatment to conventional radiation therapy.
THE FOLLOWING APPLIES TO CMS (MEDICARE) MEMBERS ONLY
For Proton Beam and Stereotactic Radiotherapy, refer to Local Coverage Determination (LCD), if applicable.

BACKGROUND
Most endometrial cancers are adenocarcinomas, with uterine sarcomas accounting for <10%. This clinical guideline will focus primarily on adenocarcinoma of the endometrium.

After a diagnosis of endometrial cancer is made, it is followed by a staging evaluation to determine extent of disease (local, regional, or metastatic) and prognostic findings. For patients in whom cancers of the uterus are suspected, an endometrial biopsy is typically performed.¹ A review of the pathology will determine whether the tumors are of epithelial origin (endometrioid, papillary cirrus, clear cell, or carcinosarcoma) or stromal/mesenchymal carcinoma (stromal sarcoma or leiomyosarcoma). Most endometrial cancers, however, are adenocarcinomas with tumor typically confined to the uterus. Thus, this disease is often localized with an excellent prognosis. Current workup, including a complete surgical assessment, includes a histological grade, depth of myometrial invasion, and extent of extrauterine involvement. Prognostic factors are based on a pathologic assessment and include the percent of myometrial invasion, myometrial thickness, tumor size and location (upper fundus or lower uterine cervical), cervix involvement, and lymphovascular space involvement. Most patients are treated surgically with radiation reserved for patients who are deemed at a high risk of recurrence or for those deemed medically inoperable.²

This guideline outlines several methods suitable for the employment of radiation therapy. This includes the use of 3-dimensional conformal radiation therapy and/or internal radiation (brachytherapy). IMRT is not indicated as a standard treatment option for uterine cancer. External beam treatments are typically delivered using a high-energy linear accelerator. Brachytherapy is generally delivered using temporary HDR sources such as iridium-192. The purpose of this guideline is to outline the most efficient, comparatively effective, diagnostic and treatment pathway. Treatment is typically broken down into patients in whom disease is limited to the uterus, cervical involvement (either suspected or confirmed), or extrauterine disease.³

POLICY HISTORY

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<td>January 2022</td>
<td>• Under Post-operative, changed external beam to 50.4 Gy for combination external beam and brachytherapy</td>
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<td>• Added Post-Operative IMRT under Treatment Options Requiring Additional Clinical Review</td>
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<td>Updated references</td>
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<td>February 2019</td>
<td>Added and updated references</td>
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³— Endometrial Cancer  
REFERENCES


ADDITIONAL RESOURCES


Reviewed / Approved by NIA Clinical Guideline Committee
GENERAL INFORMATION
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INDICATIONS FOR RADIATION THERAPY
Three-dimensional conformal radiation therapy (3D-CRT) is considered medically necessary for the following with the following clinical indications¹:

- Pre-operative (Potentially Resectable) T2, T3, or T4 Any N, M0 or
- Primary Therapy (Unresectable/Medically Unfit) Any N, Any T, M0 or
- Post-operative -Surgical Resection T2, T3, T4, Any N or Any T, N+ or Positive margins, or M1

Dosage Guidelines:
- 45-50.4Gy up to 28 fractions

TREATMENT OPTIONS REQUIRING PHYSICIAN REVIEW

Intensity Modulated Radiation Therapy (IMRT)¹
IMRT is not indicated as a standard treatment option and should not be used routinely for the delivery of radiation therapy for gastric cancer. IMRT is strictly defined by the utilization of inverse planning modulation techniques. IMRT may be appropriate for limited circumstances in which radiation therapy is indicated and 3D conformal radiation therapy (3D-CRT) techniques cannot adequately deliver the radiation prescription without exceeding normal tissue radiation tolerance, the delivery is anticipated to contribute to potential late toxicity or tumor volume dose heterogeneity is such that unacceptable hot or cold spots are created. The role of intensity modulated radiation therapy, according to current National Comprehensive Cancer Network Guidelines may be appropriate in selected cases to reduce dose to normal structures, such as heart, lungs, kidneys, and liver. However, uncertainties from variations in stomach filling and respiratory motion need to be considered.

Clinical rationale and documentation for performing IMRT rather than 2D or 3D-CRT treatment planning and delivery will need to:

¹—Gastric Cancer
• Demonstrate how 3D-CRT isodose planning cannot produce a satisfactory treatment plan (as stated above) via the use of a patient-specific dose volume histograms and isodose plans.

• Provide tissue constraints for both the target and affected critical structures.

Proton Beam Radiation Therapy
Proton beam is not an approved treatment option for gastric cancer. There are limited clinical studies comparing proton beam therapy to 3-D conformal radiation. Overall, studies have not shown clinical outcomes to be superior to conventional radiation therapy.

Stereotactic Body Radiation Therapy
Stereotactic Body Radiation Therapy (SBRT) is not an approved treatment option for the treatment of gastric cancer.

BACKGROUND
For patients with resectable gastric cancer, radiation therapy has been used both in the pre-operative and post-operative settings. External beam radiation therapy alone is of limited use for patients with locally unresectable gastric cancer with no evidence of improved survival. Combined chemoradiation, however, does result in improved survival, and thus combined modality treatment is typically supported. The role of IMRT (intensity modulated radiation therapy) may be appropriate in selected cases to reduce dose to normal structures, such as heart, lungs, kidneys, and liver, but should be considered on a case-by-case basis.

The goal of these guidelines is to delineate appropriate indications of the employment of radiation therapy in the treatment of gastric cancer and to define suitable methods of delivery of radiation therapy for these indications.

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INDICATIONS FOR RADIATION THERAPY

2D, 3D, IMRT and Brachytherapy techniques may be used as appropriate, depending on the tumor location and stage of disease. Brachytherapy, where appropriate, may be utilized as a boost for 2D, 3D or IMRT courses of radiation therapy.

• Pre-operative radiation therapy  
  o 2D/3D/IMRT – up to 35 fractions

• Definitive radiation therapy with or without concurrent chemotherapy  
  o 2D/3D/IMRT – up to 42 fractions  
    ▪ Hyperfractionation - 81.6Gy, 1.2Gy per fraction BID (up to 68 fractions)

• Post-operative radiation therapy (up to 40 fractions)  
  o Presence of adverse factors  
    ▪ pT3 or pT4 primary tumors  
    ▪ N2-3  
    ▪ Perineural invasion  
    ▪ Vascular tumor embolism  
    ▪ Extracapsular spread  
    ▪ Positive surgical margin

• Palliative radiation therapy if symptomatic up to 20 fractions

TREATMENT OPTIONS REQUIRING PHYSICIAN REVIEW

Stereotactic Body Radiation Therapy (SBRT)  
Stereotactic Body Radiation Therapy is not a standard treatment option for the treatment of head and neck cancer. SBRT may be indicated for reirradiation.1

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1 National Imaging Associates, Inc. (NIA) is a subsidiary of Evolent Health LLC.

**Proton Beam Radiation Therapy**

Proton beam is not a standard treatment option for head and neck cancer and should not be used routinely. A physician review is required to determine medical necessity.

- Re-irradiation up to 34 fractions may be indicated if no metastatic disease present
- Advanced (e.g., T4) and/or unresectable head and neck cancers
- Cancers of the paranasal sinuses and other accessory sinuses

**BACKGROUND**

According to the American Society of Clinical Oncology, about 4% of all cancers in the United States occur in the head and neck. The majority of these tumors are squamous cell carcinoma, with human papilloma virus infection, tobacco and alcohol use regarded as risk factors. Due to the complexity of tumors arising from the head and neck region, it is not unusual for management to include an initial evaluation and development of a plan by a multidisciplinary team, including surgery, radiotherapy, medical oncology, and dental. Although single modality treatment with either surgery or radiotherapy is not uncommon with patients with early stage disease, combined modality therapy is appropriate for the majority of patients with locally or regionally advanced stage of disease. The primary sites for head and neck tumors include paranasal sinuses, the lip, oral cavity, salivary glands, oropharynx, hypopharynx, glottic larynx, supraglottic larynx, nasopharynx, and occult head and neck primary sites.

This guideline outlines several methods suitable for delivering radiation therapy to the head and neck area. Various radiotherapy techniques may be used as appropriate, depending on the stage, location, and expertise of the radiation oncologist. Multidisciplinary management is recommended to best achieve tumor control while reducing toxicity. These are generally accepted practice guidelines, however, and cannot incorporate all possible clinical variations. Thus, they are not intended to replace good clinical judgment or individualization of treatments.

IMRT, 3D, 2D, and brachytherapy techniques may be used as appropriate, depending on the tumor location, stage of disease, and experience/availability of dosimetry/medical physics support. Intensity modulated radiation therapy (IMRT) has been shown to be useful in reducing long-term side effects in oropharyngeal, paranasal sinus, and nasopharyngeal cancers by reducing dose to normal surrounding tissue, including the salivary gland and brain (including temporal lobes, auditory apparatus, and optic structures). The application of IMRT to other sites of the head and neck is evolving with the recommendation to use at the discretion of the treating physicians. IMRT can be delivered with various dose fractionation schemes, including simultaneous integrated boost, sequential boost, and concomitant accelerated boost. IMRT has been shown to be beneficial in treating certain head and neck cancers by reducing dose to the salivary glands, brain, auditory apparatus, and optic structures. Low dose or high dose brachytherapy may be appropriate in certain cases.
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<td>• Cancers of the paranasal sinuses and other accessory sinuses</td>
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<tr>
<td>February 2020</td>
<td>• Proton Beam Added: Proton beam is not a standard treatment option for head and neck cancer and should not be used routinely. Proton Beam</td>
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<td>may be considered for advanced (e.g. T4) and/ or unresectable head and neck cancers.</td>
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REFERENCES


**ADDITIONAL RESOURCES**


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GENERAL INFORMATION
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INDICATIONS FOR RADIATION THERAPY AND TREATMENT OPTIONS

2D and 3D conformal radiation therapy techniques are considered medically necessary for treatment of Hodgkin Lymphoma.¹

**Stage I-II (nonbulky disease)**
- Chemotherapy + radiation therapy (20-30Gy) up to 20 fractions

**Stage IIB-IIIB (nonbulky disease)**
- Chemotherapy + radiation therapy (30Gy) up to 20 fractions

**Stage I-IV (bulky disease)**
- Chemotherapy + radiation therapy (30-36Gy) up to 24 fractions

**Palliative**
- Up to 10 fractions of external radiation may be indicated for symptom control

Radiation therapy alone is uncommon (except for lymphocyte predominant Hodgkin lymphoma). If used, doses of 30-36Gy (up to 20 fractions) is recommended for uninvolved regions, 25-30Gy (up to 17 fractions)

TREATMENT OPTIONS REQUIRING PHYSICIAN REVIEW

**Intensity Modulated Radiation Therapy (IMRT)**
IMRT is not indicated as a standard treatment option and should not be used routinely for the delivery of radiation therapy for Hodgkin lymphoma. IMRT is strictly defined by the utilization of inverse planning modulation techniques. IMRT may be appropriate for limited circumstances in which radiation therapy is indicated and 3D conformal radiation therapy (3D-CRT) techniques cannot adequately deliver the radiation prescription without exceeding normal tissue radiation tolerance, the

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¹ National Imaging Associates, Inc. (NIA) is a subsidiary of Evolent Health LLC.
delivery is anticipated to contribute to potential late toxicity or tumor volume dose heterogeneity is such that unacceptable hot or cold spots are created.

Clinical rationale and documentation for performing IMRT rather than 2D or 3D-CRT treatment planning and delivery will need to:

- Demonstrate how 3D-CRT isodose planning cannot produce a satisfactory treatment plan (as stated above) via the use of patient-specific dose volume histograms and isodose plans.

- Provide tissue constraints for both the target and affected critical structures.

NCCN panel recommends limiting Mean Lung Dose to < 13.5Gy, V20 <30%, and V5 <55%.

**Stereotactic Body Radiation Therapy**

Stereotactic Body Radiation Therapy (SBRT) is not currently a routine treatment option for the treatment of Hodgkin’s lymphoma. SBRT may be appropriate for patients with tumors arising in or near a previously irradiated region to minimize risk to surrounding normal tissues. If requested, this would require peer to peer review to determine medical necessity.

**Proton Beam Radiation Therapy**

Proton beam is not an approved treatment option for Hodgkin Lymphoma. Proton beam has not been proven superior treatment to conventional radiation therapy.

**THE FOLLOWING APPLIES TO CMS (MEDICARE) MEMBERS ONLY**

*For Proton Beam and Stereotactic Radiotherapy, refer to Local Coverage Determination (LCD), if applicable.*

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**BACKGROUND**

Due to the significant improvement in treatment for this disease, Hodgkin disease is further classified into classical Hodgkin lymphoma (that accounts for 95% of all Hodgkin cases) and lymphocyte predominant Hodgkin lymphoma. Staging for Hodgkin lymphoma is based on the Ann Arbor staging system (stage I-IV), further subdivided into “A” (no systemic symptoms presents) and “B” (weight loss of >10%, fevers, or night sweats). Unfavorable prognostic factors include bulky mediastinal disease, nodal mass >10 cm, numerous sites of disease, significantly elevated erythrocyte sedimentation rate, or B symptoms. Treatment recommendations are typically based on three subgroups of Hodgkin lymphoma: early stage favorable (stage I-II with no unfavorable factors), early stage unfavorable (stage I-II with any unfavorable factors as mentioned above), and advanced stage disease (stage III and IV). When radiation therapy is used for the treatment of Hodgkin disease, it is usually in combination with chemotherapy. If chemotherapy is used alone, radiation therapy can be used for relapse.
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INDICATIONS FOR HYPERTHERMIA WITH RADIATION THERAPY

- Superficially recurrent melanoma
- Chest wall recurrence of breast cancer
- Recurrent cervical lymph nodes from head and neck cancer

FREQUENCY OF PROCEDURE

A maximum of ten (10) hyperthermia treatments may be delivered two times per week at 72 hour intervals.

CONTRAINDICATIONS FOR HYPERTHERMIA

- The use of intraluminal, endocavitary, interstitial, regional deep tissue hyperthermia exceeding 4 cm. in depth and whole body hyperthermia are considered investigational.
- There can not be any evidence of depth of tumor recurrence greater than 4 cm.
- There can be no evidence of metastatic disease for which systemic chemotherapy or hormonal therapy is planned or being given.

NOTE: Hyperthermia is not approvable when used alone or in conjunction with chemotherapy.

BACKGROUND

Hyperthermia in combination with radiation therapy has FDA approval for the “palliative management of certain solid surface and subservice malignant tumors (i.e. melanoma, squamous or basal cell tumors, adenocarcinoma, or sarcoma) that are progressive or recurrent despite conventional radiation therapy.” The National Cancer Center Network recommends the use of hyperthermia be limited to treatment centers with appropriate training, expertise, and equipment.

OVERVIEW

(Adapted from the National Cancer Institute)

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1—Hyperthermia

Hyperthermia is a treatment for cancer in which body tissue is exposed to high temperatures. Research has shown that hyperthermia can damage and kill cancer cells in some circumstances when it is used with radiation therapy.

**Local Hyperthermia** - Heat is applied to a small area only. Local hyperthermia is typically administered every 72 hours (i.e., twice a week) for a total of 10 to 12 treatments using applicators that are placed close to, or in, the tumor. Local hyperthermia can be administered using various techniques: external, intraluminal or endocavitary, and interstitial.

- **External Hyperthermia** - This technique is used for cancers that are on, or just below, the skin. The tumor is heated externally using applicators that are placed on, or near to, the affected area. Heat is then applied using high-frequency energy waves generated from a device outside the body (such as a microwave or ultrasound).
- **Intraluminal or Endocavitary Hyperthermia** - This technique may be used to treat cancers that are within or near to body cavities. A sterile probe that can be heated is placed inside the cavity where the tumor is. This heats the affected area.
- **Interstitial Hyperthermia** - This is used to treat tumors that are deep within the body. Under anesthetic, probes or wires are placed within the tumor tissue and then heated. This method allows tumors to be heated to a higher temperature than external techniques.

**Regional Hyperthermia** - Various approaches may be used to heat large areas of tissue, such as a body cavity, organ, or limb. This includes all of the following:

- **Deep Tissue** - This may be used to treat cancers within the body, such as cervical or bladder cancer. External applicators are positioned around the body cavity or organ to be treated, and microwave or radiofrequency energy is focused on the area to raise its temperature.
- **Regional perfusion** - In this procedure, some of the patient’s blood is removed, heated, and then perfused back into the limb or organ.
- **Continuous hyperthermic peritoneal perfusion (CHPP)** - This is a technique used to treat cancers within the peritoneal cavity. During surgery, heated chemotherapy drugs flow from a warming device through the peritoneal cavity. The peritoneal cavity temperature reaches 106–108°F.

**Whole-body hyperthermia** - used to treat metastatic cancer. This can be accomplished by several techniques that raise the body temperature to 107–108°F, including the use of thermal chambers or hot water blankets.

**Additional Terminology:**
Hyperthermia is also called thermal therapy or thermotherapy.
### POLICY HISTORY

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Most requests for radiation therapy are addressed by NIA treatment site clinical guidelines. However, there may be requests that are not. For such requests, determinations will be made on a case-by-case basis utilizing the following guidelines (when applicable) but not limited to: National Comprehensive Cancer Network (NCCN), American Society for Radiation Oncology ASTRO (i.e., Model Policies; Evidence-Based Consensus Statement), ACR Appropriateness Criteria, American Society of Clinical Oncology (ASCO) and/or peer reviewed literature.

This IMRT guideline applies to other cancers not addressed by NIA treatment site clinical guidelines.

Refer to applicable treatment site-specific guidelines for the management of primary malignancies. Applicable site-specific guidelines may include all or some of the sites below.

- Anal Cancer
- Bone Metastases
- Breast Cancer
- Cervical Cancer
- CNS Cancer
- Colon Cancer
- Rectal Cancer
- Endometrial Cancer
- Gastric Cancers
- Head and Neck Cancer
- Lung – Non-Small Cell
- Lung - Small Cell Lung Cancer
- Lymphoma - Hodgkin’s Lymphoma
- Lymphoma - Non-Hodgkin’s Lymphoma
- Pancreas Cancer
- Prostate Cancers

For metastasis to the brain, regardless of primary site, refer to the NIA clinical guideline for Central Nervous System (CNS).

For metastasis to bone, refer to the NIA clinical guideline for Bone Metastases.

For all other metastases, refer to the NIA clinical guideline for Metastatic disease.
MEDICALLY NECESSARY INDICATIONS FOR INTENSITY-MODULATED RADIATION THERAPY (IMRT)¹:

- Anal cancer (or low-lying rectal cancer treated like anal cancer)
- Esophageal cancer
- Prostate cancer
- Trachea cancer
- Thyroid cancer
- Head and neck cancer
- CNS lesions with close proximity to the optic nerve, lens, retina, optic chiasm, cochlea or brain stem. (See NIA CNS Clinical Guidelines)
- Primary Bone and Articular Cartilage cancer of the skull and face, vertebral column, sacrum, and coccyx
- Treatment for repeat irradiation of a field that has received prior irradiation
- Vulvar cancer
- Pediatric patients less than 21 years with a radiosensitive tumor
- Bladder cancer (other than palliative cases)

CONDITIONS REQUIRING ADDITIONAL PHYSICIAN REVIEW

IMRT is not indicated as a standard treatment option and should not be used routinely for the delivery of radiation therapy for all other conditions including, but not limited to¹:

- Breast cancer
- Colon cancer
- Gastric cancer
- Gynecological cancer
- Lung cancer
- Lymphoma
- Pancreas cancer
- Pelvic bone cancer
- Primary or secondary liver cancer
- Rectal cancer
- Secondary bone and articular cartilage cancer
- Soft tissue sarcoma
- All other neoplasms not listed above as medically necessary

IMRT may be indicated for the above conditions if ALL of the following are present¹:

IMRT is strictly defined by the utilization of inverse planning modulation techniques. IMRT may be appropriate for limited circumstances in which radiation therapy is indicated and 3D conformal radiation therapy (3D-CRT) techniques cannot adequately deliver the radiation prescription without exceeding normal tissue radiation tolerance, the delivery is anticipated to contribute to potential late
toxicity or tumor volume dose heterogeneity is such that unacceptable hot or cold spots are created. If IMRT is utilized, techniques to account for respiratory motion should be performed when appropriate.

Clinical rationale and documentation for performing IMRT rather than 2D or 3D-CRT treatment planning and delivery will need to:

- Demonstrate how 3D-CRT isodose planning cannot produce a satisfactory treatment plan (as stated above) via the use of patient-specific dose volume histograms and isodose plans. 3D-CRT techniques, such as step-and-shoot or field-in-field, should be considered for the comparison.
- Confirm the IMRT requested will be inversely planned (forward plans or 'field-in-field' plans are not considered IMRT).
- Provide tissue constraints for both the target and affected critical structures.

**Postoperative IMRT for Endometrial Cancer**
IMRT for post-operative radiation therapy is approvable. If there is gross residual disease and the area(s) can be sufficiently utilized, a boost can be added to a total dose of 60-70Gy, respecting normal tissue sensitivity. For gross nodal disease, consider boost to 60-65Gy while respecting normal tissue constraints.²

**Postoperative IMRT for Cervical Cancer**
IMRT for post-operative radiation therapy is approvable. If there is gross residual disease and the area(s) can be sufficiently utilized, a boost can be added to a total dose of 60-70Gy, respecting normal tissue sensitivity. For gross nodal disease, consider boost to 60-65Gy while respecting normal tissue constraints.³⁻⁵

**Hippocampal Sparing Intensity Modulated Radiation Therapy for PCI**⁶⁻⁸
The use of hippocampal avoidance with WBRT, using IMRT, lowers the risks of neurocognitive decline (specifically memory and recall), and now supported with level 1 evidence.

- **Dosage Guidelines**
  - 25Gy in 10 fractions is considered medically necessary

**Hippocampal Sparing Whole Brain Intensity Modulated Radiation Therapy**⁷,⁹⁻¹¹

- Hippocampal sparing whole brain IMRT is considered medically necessary for metastatic brain lesions in individuals with all of the following:
  - Good performance status: ECOG rating is less than 3
  - Who have a prognosis of at least 4 months
  - no metastases within 5mm of the hippocampi
  - have not had prior WBRT or external beam radiation to the brain
Stage IIIB Non-Small Cell Lung Carcinoma (any N3, or T3/4N2)\textsuperscript{12}
IMRT is approvable for definitive treatment of stage IIIB (any N3, or T3/4N2) NSCLC. A comparative plan is not required.

Accelerated Partial Breast Irradiation (APBI)\textsuperscript{13,14}
Upon physician review, IMRT can be approved for accelerated partial breast irradiation using 30Gy in 5 fractions once a day regimen. Comparative 3D-CRT vs. IMRT plans is not required.

BACKGROUND
Intensity-Modulated Radiation Therapy (IMRT) is a computer-based method of planning for and delivery of, generally narrow, patient-specific, spatially, and often temporally modulated beams of radiation to solid tumors within a patient. IMRT planning and delivery uses an approach for obtaining the highly conformal dose distributions needed to irradiate complex targets positioned near, or invaginated by, sensitive normal tissues, thus improving the therapeutic ratios. IMRT delivers a more precise radiation dose to the tumor while sparing the surrounding normal tissues by using non-uniform radiation beam intensities that are determined by various computer-based optimization techniques. The computer-based optimization process is referred to as “inverse planning.” Inverse planning develops a dose distribution based on the input of specific dose constraints for the Planned Treatment Volume (PTV) and nearby clinical structures and is the beginning of the IMRT treatment planning process. The Gross Tumor Volume (GTV), the PTV and surrounding normal tissues must be identified by a contouring procedure and the optimization must sample the dose with a grid spacing of 1 cm or less. Traditional “field-in-field technique,” which is neither MLC nor compensator-based, is not considered IMRT but rather external beam therapy.

The decision process for using IMRT requires an understanding of accepted practices that take into account the risks and benefits of such therapy compared to conventional treatment techniques. While IMRT technology may empirically offer advances over conventional or 3-D conformal radiation, a comprehensive understanding of all consequences is required before applying this technology. IMRT is not a replacement therapy for conventional radiation therapy methods.

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REFERENCES


**ADDITIONAL RESOURCES**


12. Eccles CL, Bissonnette JP, Craig T, Taremi M, Wu X, Dawson LA. Treatment planning study to determine potential benefit of intensity-modulated radiotherapy versus conformal radiotherapy for


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INDICATIONS FOR IORT

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**Breast Cancer:** Refer to NIA’s clinical guideline on Breast Cancer.
- Single Fraction Electron-beam IORT is considered medically necessary in accordance with ASTRO guidelines if the following criteria are met:
  - Individual is 50 years of age or older with invasive cancer
  - T Stage: Tis or T1
  - Clinically node negative
  - Negative surgical margins

- The use of electronic brachytherapy for IORT (such as Intrabeam, Xoft and Papillon systems) is considered experimental, investigational, and/or unproven.

**Cervical Cancer:** Refer to NIA’s clinical guideline on Cervical Cancer. IORT is indicated for local or regional recurrence of cervical cancer for centralized disease when previous radiation therapy has occurred.

**Colon Cancer:** Refer to NIA’s clinical guideline on Colorectal Cancer. IORT can be used as a boost for recurrent cancer of T4 tumors with penetration/perforation and intermediate/positive margins. IORT can also be used as a boost for recurrent cancer.
**Pancreatic Cancer:** Refer to NIA’s clinical guideline on Pancreatic Cancer. IORT for pancreatic cancer requires review by a physician and may be reasonable for patients undergoing resection that may result in a closer involved margin.4

**Rectal Cancer:** Refer to NIA’s clinical guideline on Colorectal Cancer. IORT is indicated for rectal cancer with positive or close margins for T4 lesions or recurrent disease.5

**Soft Tissue Sarcoma:** IORT (with photons or electrons is considered medically necessary as boost treatment at time of surgery for cervical cancer, colorectal cancer, pancreatic cancer, and soft tissue sarcomas if either of the following criteria is met6:
- Tumor has a high risk of recurring; **OR**
- Tumor cannot be completely removed (positive margins)

**FREQUENCY OF PROCEDURE:**
- A single fraction is allowed during surgery for the above situations.

**CONTRAINDICATIONS FOR IORT**

IORT is not indicated for any other cancer sites or scenarios other than those listed above, or when the above indications are not met. All other scenarios are considered investigational and not medically necessary.

**BACKGROUND**

Intraoperative Radiation Therapy (IORT) is a radiation treatment that is administered during surgery. It allows delivery of radiation directly to the target area for cancers that are difficult to remove during surgery or in situations in which there may be microscopic amounts of cancer remaining after removal. IORT delivers higher doses of radiation than can be used in conventional radiation therapy because the doctor can temporarily move nearby organs or shield them from radiation exposure.

IORT is often combined with conventional radiation therapy which is typically given prior to or during surgery.

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INDICATIONS FOR THE TREATMENT OF METASTASIS

BRAIN: For metastasis to the brain, regardless of primary site, refer to the NIA clinical guideline for Central Nervous System (CNS).

BONE: For metastasis to bone, refer to the NIA clinical guideline for bone metastases.

LUNG¹:

- Conventional 2D and 3D-CRT treatment delivery is appropriate for all other secondary malignancies up to ten (10) to fifteen (15) fractions.
  - Treatment beyond ten fractions for 2D-3D-CRT requires physician review and a clinical rationale for additional fractions

ALL OTHER SITES: For metastasis to any other site other than brain, lung, or bone:

- Conventional 2D and 3D-CRT treatment delivery is appropriate for all other secondary malignancies up to ten (10) fractions.²
  - Treatment beyond ten fractions for 2D-3D-CRT requires physician review and a clinical rationale for additional fractions.

TREATMENT OPTIONS REQUIRING PHYSICIAN REVIEW

- **IMRT** is not indicated for treatment of metastasis except for limited circumstances in which radiation therapy is indicated and 3D conformal radiation therapy (3D-CRT) techniques cannot adequately deliver the radiation prescription without exceeding normal tissue radiation tolerance, the delivery is anticipated to contribute to potential late toxicity or tumor volume dose

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¹ National Imaging Associates, Inc. (NIA) is a subsidiary of Magellan Healthcare, Inc.

² Metastatic Disease

heterogeneity is such that unacceptable hot or cold spots are created. If IMRT is utilized, techniques to account for respiratory motion should be performed when appropriate.

- Clinical rationale and documentation for performing IMRT rather than 2D or 3D-CRT treatment planning and delivery will need to:
  - Demonstrate how 3D-CRT isodose planning cannot produce a satisfactory treatment plan (as stated above) via the use of patient-specific dose volume histograms and isodose plans. 3D-CRT techniques such as step-and-shoot or field-in-field should be considered for the comparison.
  - Confirm the IMRT requested will be inversely planned (forward plans or ‘field-in-field’ plans are not considered IMRT).

- **Selective Internal Radiation Therapy (SIRT),** also known as radioembolization with microsphere brachytherapy device (RMBD) and transarterial radioembolization, uses microscopic radioactive spheres to deliver radiation to the tumor site. Treatment is delivered through catheter injection of radioactive Yttrium-90 (90Y) microspheres into the hepatic artery. [For Absolute Contraindication† and Relative Contraindications‡, please see the notes below.] Indications for SIRT include³,⁴:
  - Unresectable metastatic liver tumors
  - Unresectable metastatic liver tumors from primary colorectal cancer
  - Unresectable primary hepatocellular carcinoma
  - Unresectable neuroendocrine tumors

†Note: Absolute Contraindication⁵
- Fulminant liver failure (absolute)

‡Note: Considerations/Relative Contraindications⁵
- The tumor burden should be liver dominant, not necessarily exclusive to the liver
- Patients should also have a performance status that will allow them to benefit from such therapy
- A life expectancy of at least 3 months
- Excessive tumor burden in the liver with greater than 50% to 70% of the parenchyma replaced by tumor
- Total bilirubin greater than 2 mg/dL (in the absence of obstructive cause), which indicates severe liver function impairment. Nonobstructive bilirubin elevations may indicate that liver metastases have caused liver impairment to the degree that risks outweigh benefits for this therapy. In contrast, patients with HCC and elevated bilirubin may be treated with radioembolization if a segmental or subsegmental infusion can be performed
- Prior radiation therapy to the liver or upper abdomen that included a significant volume of the liver

- **Oligometastatic Disease⁶**
  - Stereotactic Body Radiation Therapy (SBRT) is medically necessary for extracranial oligometastatic disease for an individual with One (1) to Five (5) metastatic lesions when the following criteria are met:
• Good performance status: ECOG less than 3 or Karnofsky Scale greater than or equal to 70% and stable systemic disease or reasonable systemic treatment options.

• All other treatment approaches require physician review with presentation of clinical rationale and documentation for the proposed treatment modality and plan.

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| January 2022 | • Added indications for metastasis to lung  
               • Under “All Other Sites”, added “lung” to state, “For metastasis to any other site other than brain, lung, or bone”  
               • Under SIRT, added notes for absolute contraindication and considerations/relative contraindications  
               • Within Oligometastatic Disease, increased the range of metastatic lesions from “One (1) to Four (4)” to “One (1) to Five (5)” |
| February 2021| Added:  
               • Oligometastatic Disease: Stereotactic Body Radiation Therapy (SBRT) is medically necessary for extracranial oligometastatic disease for an individual with One (1) to Four (4) metastatic lesions when the following criteria are met:  
                 o Good performance status: ECOG less than 3 or Karnofsky Scale greater than or equal to 70% and stable systemic disease or reasonable systemic treatment options  
               • Added References |
| February 2020| No Changes |
| February 2019| Added and updated references |
REFERENCES


ADDITIONAL RESOURCES


Reviewed / Approved by NIA Clinical Guideline Committee
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INDICATIONS FOR NEUTRON BEAM THERAPY

- Neutron beam treatment is indicated for salivary gland cancers that are inoperable, recurrent, or are resected with gross residual disease or positive margins.¹

- Other uses of Neutron Beam Therapy are considered investigational and therefore are not approved because its effectiveness for these indications has not been established.

BACKGROUND

Neutron Beam Therapy (NBT) is a type of radiation treatment that uses a particle accelerator so is not readily available in most of the country. Protons from the accelerator create a neutron beam that attacks cancer cells with more power than conventional radiation therapy. Neutrons are much heavier than photons, thus appear to be more effective in destroying very dense tumors. With neutron beam treatment, the risk of side effects on healthy tissue near the cancer site is greater, requiring equipment to precisely focus the beam and block exposure to any surrounding tissue. Currently, both the availability and the criteria for use are very limited.

Overview:

NBT has been employed mainly for the treatment of the salivary gland cancers. It has also been used to treat other malignancies such as soft tissue sarcoma, lung, pancreatic, colon, kidney, and prostate cancers. Nevertheless, NBT has not gained wide acceptance because of the clinical difficulty in generating neutron particles and limited publications.

The safety and efficacy of neutron beam radiation therapy has not been established in the published medical literature. Complication rates were increased for NBT compared to other forms of external beam radiation therapy, and questions remain with regard to patient selection criteria, technical parameters, and comparative efficacy to other treatment modalities.

¹ National Imaging Associates, Inc. (NIA) is a subsidiary of Evolent Health LLC.
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INDICATIONS FOR RADIATION THERAPY AND TREATMENT OPTIONS:

Three-dimensional conformal radiation therapy (3D-CRT) or two-dimensional (2D) radiation therapy (2D) is the appropriate technique for treatment of Non-Hodgkin’s Lymphomas. The following include radiation dose guidelines for the following lymphomas:

- Follicular lymphoma (24-30Gy, or 36Gy if bulky) up to 24 fractions
- Mantle cell lymphoma (24-36Gy) up to 24 fractions
- MALT lymphoma – Marginal Zone (24-30Gy) up to 20 fractions
- Diffuse large B cell lymphoma (30-55Gy) up to 37 fractions
- Primary cutaneous anaplastic large cell lymphoma: 24-36Gy up to 24 fractions
- NK/T Lymphoma
  - primary treatment: 50-55Gy up to 31 fractions
  - combined modality: 45-50.4Gy up to 28 fractions
  - Localized chronic lymphocytic leukemia (CLL) and Small Lymphocytic Lymphoma (SLL): 24-30Gy up to 17 fractions
- Palliative dose (up to 10 fractions) for symptom control

Unless otherwise indicated, standard radiation fractionation consists of 1.5Gy to 2.0Gy per day.

Total Skin Electron Beam Therapy (TSEBT)

A variety of techniques, using electron beam, may be utilized to cover the entire cutaneous surface.

- Dosage Guidelines:
  - 8-36Gy, 1-2Gy per fraction, 4-5 days per week, up to 36 fractions. “Shadowed” areas may need to be supplemented with individual electron fields. Individual tumors may be boost with doses of 4-12Gy

TREATMENT OPTIONS REQUIRING PHYSICIAN REVIEW

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* National Imaging Associates, Inc. (NIA) is a subsidiary of Evolent Health LLC.

1—Non Hodgkin’s Lymphoma Rad Onc
Intensity modulated radiation therapy (IMRT)
IMRT is not indicated as a standard treatment option and should not be used routinely for the delivery of radiation therapy for Non-Hodgkin’s lymphoma. IMRT is strictly defined by the utilization of inverse planning modulation techniques. IMRT may be appropriate for limited circumstances in which radiation therapy is indicated and 3D conformal radiation therapy (3D-CRT) techniques cannot adequately deliver the radiation prescription without exceeding normal tissue radiation tolerance, the delivery is anticipated to contribute to potential late toxicity, or tumor volume dose heterogeneity is such that unacceptable hot or cold spots are created.

Clinical rationale and documentation for performing IMRT rather than 2D or 3D-CRT treatment planning and delivery will need to:

- Demonstrate how 3D-CRT isodose planning cannot produce a satisfactory treatment plan (as stated above) via the use of patient-specific dose volume histograms and isodose plans.

- Provide tissue constraints for both the target and affected critical structures.

Stereotactic Body Radiation Therapy
Stereotactic Body Radiation Therapy (SBRT) is not currently a routine treatment option for the treatment of Hodgkin’s lymphoma. SBRT may be appropriate for patients with tumors arising in or near a previously irradiated region to minimize risk to surrounding normal tissues. If requested, this would require peer to peer review to determine medical necessity.

Proton Beam Radiation Therapy
Proton beam is not an approved treatment option for Non-Hodgkin’s Lymphoma. Proton beam has not been proven superior treatment to conventional radiation therapy.

THE FOLLOWING APPLIES TO CMS (MEDICARE) MEMBERS ONLY:
For Proton Beam and Stereotactic Radiotherapy, refer to Local Coverage Determination (LCD), if applicable.

BACKGROUND
The incidence of non-Hodgkin’s lymphomas has increased substantially over the past few decades due to age-related disease. The majority of non-Hodgkin’s lymphoma originates in B-lymphocytes (80-85%) with T-lymphocytes comprising 15-20%. Natural killer cell lymphomas are very rare. The classification of non-Hodgkin’s lymphoma is based on the cell of origin (large B, large T, or large NK), precursor or mature lymphocytes, as well as genetic, immunophenotype, and clinical features. Radiation therapy is typically delivered to the involved field either alone or in consolidation following chemotherapy. CT-based simulation and 3-dimensional planning is typically advised.

The use of intensity modulated radiation therapy, as well as stereotactic body radiotherapy would be unusual. If requested, this would require peer to peer review to determine medical necessity. For
nodal sites, radiation therapy alone or consolidation following chemotherapy should treat the involved field in most cases. Regional/ extended fields are typically not recommended.

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<td>January 2022</td>
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<td>February 2021</td>
<td>Deleted: Stereotactic Body Radiation Therapy (SBRT) is not currently an approved treatment option for the treatment of Non-Hodgkin’s Lymphoma. Recent studies comparing SBRT conventional radiation therapy are limited. Added: Stereotactic Body Radiation Therapy (SBRT) is not currently a routine treatment option for the treatment of Hodgkin’s lymphoma. SBRT may be appropriate for patients with tumors arising in or near a previously irradiated region to minimize risk to surrounding normal tissues. (ASTRO 2014). If requested, this would require peer to peer review to determine medical necessity.</td>
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INDICATIONS FOR RADIATION THERAPY

Three-dimensional conformal radiation therapy (3D-CRT) is considered medically necessary for the following clinical indications:

- Post-Operative Radiation Therapy:
  - Positive Nodes (N 1-3); OR
  - Positive or close margins
  **Dosage Guidelines:**
    - Extracapsular nodal extension or positive margins: 54-60Gy up to 33 fractions
    - Gross Residual Tumor 60-70Gy up to 39 fractions
    - Negative margins: 50-54Gy up to 30 fractions

- Pre-Operative Radiation Therapy:
  - T3-4, N0-N1 or
  - Resectable Superior Sulcus Tumors or
  - N2 disease (Stage IIIA, T 1-3, N2)
  **Dosage Guidelines:**
    - 45-54Gy up to 30 fractions

- Inoperable – Definitive:
  - Stage I disease (T1-2a, N0, M0)
  - Stage II and Stage III disease (T2b-T4, N0, M0 or T1-4, N1-3, M0)
    - Surgery Refused
  **Dosage Guidelines:**
    - 60-70Gy up to 39 fractions

- Palliative Radiation Therapy is considered medically necessary for Stage IV (M1) disease to relieve pain, airway or endobronchial obstruction, and other symptoms

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Unless otherwise indicated, standard radiation fractionation consists of 1.8Gy to 2.0Gy per day. For hypofractionated palliative radiation, standard radiation fractionation consists of 2.5-3Gy.

**Stereotactic Body Radiation Therapy (SBRT)** is considered medically necessary for patients with inoperable Stage I or II disease or patients who refuse to have surgery or for a previously irradiated field¹

**Dosage Guidelines:**
- Delivered at 5 fractions or less

**Endobronchial Brachytherapy** is considered medically necessary for the following clinical indications²:
  - Patients with primary tumors who are not otherwise candidates for surgical resection or external-beam radiation therapy due to co-morbidities or location of the tumor
  - Palliative therapy for airway obstruction or severe hemoptysis in patients with primary, metastatic, or recurrent tumors.

**IMRT – Stage IIIB (any N3, or T3/4N2)**²
  - IMRT is approvable for definitive treatment of stage IIIB (any N3, or T3/4N2) NSCLC. A comparative plan is not required.

**TREATMENT OPTIONS REQUIRING PHYSICIAN REVIEW**

**Intensity Modulated Radiation Therapy (IMRT)**
IMRT is not indicated as a standard treatment option and should not be used routinely for the delivery of radiation therapy for non-small cell lung cancer. IMRT may be appropriate for limited circumstances in which radiation therapy is indicated and 3D conformal radiation therapy (3D-CRT) techniques cannot adequately deliver the radiation prescription without exceeding normal tissue radiation tolerance, the delivery is anticipated to contribute to potential late toxicity or tumor volume dose heterogeneity is such that unacceptable hot or cold spots are created. If IMRT is utilized, techniques to account for respiratory motion should be performed.

Clinical rationale and documentation for performing IMRT rather than 2D3D-CRT treatment planning and delivery will need to:

- Demonstrate how 2D-3D-CRT isodose planning cannot produce a satisfactory treatment plan (as stated above) via the use of a patient-specific dose volume histograms and isodose plans.
- Provide tissue constraints for both the target and affected critical structures.

**Proton Beam Radiation Therapy (PBT)**
Proton Beam is not indicated as a standard treatment option and should not be used routinely for the delivery of radiation therapy for non-small cell lung cancer.

**Stereotactic Body Radiation Therapy**
Stereotactic Body Radiation Therapy (SBRT) is not considered a standard form of treatment for NSCLC except for inoperable Stage I and II disease or for treatment of previously irradiated field. Other requests for SBRT will require a peer review to make a medical necessity determination. Documentation from the radiation oncologist must include the clinical rationale for performing SBRT rather than 3-D conformal treatment.

THE FOLLOWING APPLIES TO CMS (MEDICARE) MEMBERS ONLY:

For Proton Beam Radiation, refer to Local Coverage Determination (LCD), if applicable.

BACKGROUND

Lung cancer is the leading cause of cancer-related deaths of both men and women in the United States. The World Health Organization divides lung cancer into two types: non-small cell lung cancer (NSCLC) as discussed in this guideline and small cell lung cancer (SCLC). The most common lung cancer, NSCLC, includes various histologies: squamous carcinoma, adenocarcinoma, and large cell carcinoma. Surgery alone has been the standard treatment for patients with resectable NSCLC for many years. However, patients with completely resected disease have disappointing survival rates. In some cases, relapse occurs at distant sites which suggest that NSCLC may be a systemic disease when diagnosed. Chemotherapy and radiation therapy are now treatment considerations in both the preoperative and postoperative settings.

Prognosis and treatment of NSCLC are based on the staging of the cancer which documents the extent of cancer growth and spread. The initial goal of staging is to determine if the tumor is surgically resectable. Some patients with resectable disease may be cured by surgery while others, due to contraindications to surgery, may be candidates for radiation therapy for curative intent or for local control.

This guideline outlines several methods suitable for the delivery of radiation therapy to treat lung cancer. These include the use of external beam radiation therapy such as: three-dimensional conformal radiation therapy (3D-CRT), endobronchial brachytherapy, postoperative radiation therapy (PORT) and stereotactic body radiation (SBRT). Endobronchial brachytherapy and SBRT are aggressive approaches justified, in part, for non-resectable tumors. While these advances in treatment offer a range of regimens, the goal of this guideline is to guide diagnosis and treatment to the most efficient, comparatively effective, diagnostic and treatment pathway. Except for medically inoperable tumors and extreme palliative circumstances, radiation treatment is performed, in most cases, in conjunction with surgical intervention.
**POLICY HISTORY**

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| January 2022 | • Within Palliative Radiation Therapy, added “For hypofractionated palliative radiation, standard radiation fractionation consists of 2.5-3Gy.”  
              • Added IMRT – Stage IIIB (any N3, or T3/4N2)                      |
| February 2021 | Previous Guideline:  
                  Stereotactic Body Radiation Therapy (SBRT) is considered medically necessary for patients with inoperable Stage I or II disease or patients who refuse to have surgery (NCCN 2019)  
                  Updated Guideline to include medical necessity for “previously irradiated field”:  
                  **Stereotactic Body Radiation Therapy (SBRT)** is considered medically necessary for patients with inoperable Stage I or II disease or patients who refuse to have surgery or **for a previously irradiated field (NCCN, 2021).**  
                  • Updated References                                                |
| February 2020 | No Changes                                                             |
| February 2019 | Added and updated references                                          |
REFERENCES


ADDITIONAL RESOURCES


Reviewed / Approved by NIA Clinical Guideline Committee

5—Non-Small Cell Lung Cancer
GENERAL INFORMATION
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INDICATIONS FOR RADIATION THERAPY

2D or 3D Conformal (3D CRT) is considered medically necessary for several non-malignant conditions, including but not limited to:

- Prevention of keloid scars as an adjunctive therapy following excisional surgery
- Heterotopic ossification
- Pterygium in cases that cannot be medically managed
- Villonodular synovitis

Stereotactic Radiation Therapy (SRS, SBRT) is considered medically necessary when used in the treatment of non-malignant cranial lesions including the following:

- Arteriovenous malformation (AVM) of the brain or spine
- Trigeminal neuralgia that has not responded to other, more conservative, treatments
- Non-cancerous brain tumors such as acoustic neuroma, benign schwannomas, meningioma, hemangioma, pituitary adenoma, craniopharyngioma, neoplasm of the pineal gland, and chordomas

Also refer to NIA Stereotactic Radiation Therapy Guideline.

TREATMENT OPTIONS REQUIRING PHYSICIAN REVIEW

Treatment for other non-malignant conditions utilizing proton beam, stereotactic radiation therapy (SBRT), or intensity modulated radiation therapy (IMRT) modalities should be referred to physician review.

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1— Non-Cancerous Conditions

BACKGROUND
Radiation therapy may have appropriate use in several non-malignant conditions. The treatment goal in patients with non-malignant conditions is to achieve relief of the indicated condition with radiation therapy with minimal risk of radiation exposure to sensitive structures.

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INDICATIONS FOR RADIATION THERAPY

2D and 3D conformal radiation therapy techniques are considered medically necessary for treatment of pancreatic cancer.

Neoadjuvant (Pre-Operative) or Resectable or Borderline Resectable without evidence of metastatic\(^1\)
- No standard treatment regimen currently exists for this subset of patients. If neoadjuvant radiation therapy is delivered, a dose of 45-54Gy in 1.8-2.5Gy fractions or 36Gy in 2.4 fractions are viable options.

Adjuvant (Post-Operative) Resectable Without Evidence of Metastatic Disease\(^1\)
- For resected cases (45-46Gy in 1.8-2Gy fractions) to the clinical target volume, followed by boost (5-9Gy). Up to 31 fractions.

Unresectable/Locally Advanced Without Evidence of Metastatic Disease\(^1\)
- Radiation delivered in 45-54Gy (1.8-2.5Gy fractions or 36Gy in 2.4 fractions). Up to 30 fractions.

Palliative\(^1\)
- Radiation delivered in 25-36Gy in 2.4-5.0Gy fractions is usual for patients with metastatic disease who require palliation for obstruction or pain. Up to 15 fractions.

Local Recurrence after Resection without Evidence of Systemic Metastatic Disease
- Adjuvant chemotherapy or chemoradiation if no previous radiation given. Up to 30 fractions.\(^1\)

TREATMENT OPTIONS REQUIRING PHYSICIAN REVIEW

Intensity Modulated Radiation Therapy (IMRT)
IMRT is not indicated as a standard treatment option and should not be used routinely for the delivery of radiation therapy for pancreatic cancer. IMRT is strictly defined by the utilization of inverse planning

\(^1\) National Imaging Associates, Inc. (NIA) is a subsidiary of Evolent Health LLC.

1—Pancreatic Cancer
modulation techniques. IMRT may be appropriate for limited circumstances in which radiation therapy is indicated and 3D conformal radiation therapy (3D-CRT) techniques cannot adequately deliver the radiation prescription without exceeding normal tissue radiation tolerance, the delivery is anticipated to contribute to potential late toxicity or tumor volume dose heterogeneity is such that unacceptable hot or cold spots are created.

Clinical rationale and documentation for performing IMRT rather than 2D or 3D-CRT treatment planning and delivery will need to:

- Demonstrate how 3D-CRT isodose planning cannot produce a satisfactory treatment plan (as stated above) via the use of patient-specific dose volume histograms and isodose plans.
- Provide tissue constraints for both the target and affected critical structures.

Per RTOG 1102,² ³ for neoadjuvant, definitive, palliative, and recurrent disease, not more than 30% of the total volume of kidneys can received ≥18Gy. If only one kidney is functional, not more than 10% of the volume can receive ≥18Gy. Maximum dose to stomach, duodenum, and jejunum is 55Gy. Mean dose of liver cannot exceed 30Gy. Maximum dose to D0.03cc of spinal cord must be ≤45Gy.

Per RTOG 0848,⁴ for adjuvant therapy, mean dose to bilateral kidneys must be < 18Gy. If only one kidney is functional, not more than 15% of that kidney can receive ≥18Gy, and not more than 30% can received ≥14Gy. Maximum dose to stomach, duodenum, and jejunum is ≤54Gy, < 10% of each organ volume can receive between 50 and 53.99Gy, < 15% of the volume of each organ can received between 45 and 49.99Gy. Mean dose of liver must be ≤25Gy. Maximum dose to D0.03cc of spinal cord must be ≤45Gy.

**Stereotactic Body Radiation Therapy (SBRT)**¹
Stereotactic Body Radiation Therapy (SBRT) is appropriate to treat locally advanced or recurrent disease without evidence of distant metastasis or to treat a previously irradiated field.

**Proton Beam Radiation Therapy**
Proton beam is not an approved treatment option for pancreatic cancer. Proton beam has not been proven a superior treatment to conventional radiation therapy.

**Intra Operative Radiation Therapy (IORT)**
The role of intraoperative radiation therapy for pancreatic cancer is controversial but may be reasonable for patients undergoing resection that may result in closer involved margins. IORT may be considered on a case-by-case basis.

**BACKGROUND**
Pancreatic cancer typically occurs later in life. Risk factors include smoking, alcohol use, obesity, diabetes, and certain chemical exposures. Pancreatitis has also been shown to have an increased risk

— Pancreatic Cancer
of developing pancreatic cancer. Surgical resection is potentially the only curative approach, but most patients present with more advanced stage disease. Overall, the actuarial five-year survival rate is approximately 20%.

The goal of these guidelines is to delineate appropriate indications of the employment of radiation therapy in the treatment of pancreatic cancer and to define suitable methods of delivery of radiation therapy for these indications.

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<td>Added: Dose constraints for neoadjuvant, definitive, palliative and recurrent disease based on RTOG 1102 and dose constraints for adjuvant therapy based on RTOG 0848.</td>
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| February 2021 | Deleted: Stereotactic Body Radiation Therapy (SBRT) is considered medically necessary for the treatment of pancreatic cancer. If requested a physician review is required.  
Added: Stereotactic Body Radiation Therapy (SBRT) is appropriate to treat locally advanced or recurrent disease without evidence of distant metastasis or to treat a previously irradiated field |
| February 2020 | • Stereotactic Radiation Therapy:  
Deleted: Stereotactic Body Radiation Therapy (SBRT) is not currently an approved treatment option for pancreatic cancer.  
Added: Stereotactic Body Radiation Therapy (SBRT) is considered medically necessary for the treatment Pancreatic Cancer |
|               | • Added and Updated References                                          |
| February 2019 | • Added and updated references                                          |
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MEDICALLY NECESSARY INDICATIONS FOR RADIATION THERAPY

EBRT/IMRT hypofractionation of 20-28 fractions are recommended to treat localized prostate cancer when pelvic nodes are not treated. Other treatment regimens require physician review and clinical documentation that supports medical necessity.

Very Low Recurrence Risk (Primary Tumor Stage [T] is T1c, PSA <10 ng/ml, and Gleason score ≤ 6, PSA density <0.15ng/ml per g, < 3 biopsy cores positive with ≤ 50% cancer in each)

- Active surveillance (discussed with patient as treatment option)
- External Beam Radiation
  - Highly conformal radiation therapy technique (3D-CRT/IMRT with IGRT). Hypofractionation 20-28 fractions
  - SBRT delivered at five fractions or less at 6.5 Gy per fraction or greater. Appropriate as a standalone radiation modality and not as a boost to other conventional methods of radiation treatment
- LDR (low dose-rate) or HDR (high dose-rate) Brachytherapy

Low Recurrence Risk (Primary Tumor Stage [T] is T1-T2a, PSA <10 ng/ml, and Gleason score ≤ 6)

- Active surveillance (discussed with patient as treatment option)
- External Beam Radiation Therapy
  - Highly conformal radiation therapy technique (3D-CRT/IMRT with IGRT). Hypofractionation 20-28 fractions
  - SBRT delivered at five fractions or less at 6.5 Gy per fraction or greater. Appropriate as a standalone radiation modality and not as a boost to other conventional methods of radiation treatment.
- LDR (low dose-rate) or HDR (high dose-rate) Brachytherapy

Intermediate Recurrence Risk (Primary Tumor Stage [T] T2b-T2c or PSA 10-20 ng/ml or Gleason score 7)

- External Beam Radiation Therapy

---

1—Prostate Cancer Rad Onc

SBRT delivered at five fractions or less at 6.5 Gy per fraction or greater. Appropriate as a standalone radiation modality and NOT as a boost to other conventional methods of radiation treatment.

Brachytherapy (LDR/HDR) boost combined with EBRT after 20-28 fractions.

High Recurrence Risk (Primary Tumor Stage [T] T3a or PSA > 20 ng/ml or Gleason score 8-10, or two or more intermediate risk factors)

External Beam Radiation Therapy
SBRT delivered at five fractions or less at 6.5 Gy per fraction or greater. Appropriate as a standalone radiation modality and NOT as a boost to other conventional methods of radiation treatment.
Brachytherapy (LDR/HDR) boost combined with EBRT after 20-28 fractions.

Very High Recurrence Risk (Primary Tumor Stage [T] T3b-T4) with Gleason score 8-10 without Metastasis

External Beam Radiation Therapy
SBRT delivered at five fractions or less at 6.5 Gy per fraction or greater. Appropriate as a standalone radiation modality and NOT as a boost to other conventional methods of radiation treatment.
Brachytherapy (LDR/HDR) boost combined with EBRT after 20-28 fractions.

Radiation Therapy for Patients with Locally Advanced or N1 Prostate (T3b – T4, or any T and N1, M0 disease)
External Beam Radiation Therapy
Highly conformal radiation therapy technique (3D-CRT/IMRT with IGRT). Up to 45 fractions are medically necessary for localized or locally recurrent prostate cancer when pelvic nodes are treated.
Brachytherapy (LDR/HDR) boost combined with EBRT after 20-28 fractions.

Palliative Radiotherapy:
• 30Gy/10FX or
• 37.5Gy/15FX

Adjuvant Post-Prostatectomy or Salvage Radiation Therapy
External Beam Radiation Therapy
Highly conformal radiation therapy technique (3D-CRT/IMRT) Doses 64 – 72 Gy (up to 40 fractions) with IGRT
• One of the following must be met:
  o Detectable PSA or initially undetectable PSA, but with recent detectable and rising values on 2 or more measurements with no evidence of metastatic disease
  o Positive margins
  o Seminal vesicle invasion or extracapsular extension.
  o Gleason 8-10
  o Pathological T3 disease

TREATMENT OPTIONS REQUIRING PHYSICIAN REVIEW

The radiation treatment options below require review by a physician reviewer and may include deliberation on whether or not active surveillance and surgery have been considered prior to the decision to request radiation therapy:

• Brachytherapy alone (monotherapy) may be approved for Intermediate Recurrence Risk (Primary Tumor Stage [T] T2b-T2c or PSA 10-20 ng/ml or Gleason score 7) upon review with a physician reviewer. Brachytherapy alone is not considered appropriate if the patient has unfavorable or poor prognostic risk factors intermediate risk factors and is thus higher risk.

• EBRT/IMRT hypofractionation of 20-28 fractions are recommended to treat localized prostate cancer when pelvic nodes are not treated. Other treatment regimens require physician review and clinical documentation that supports medical necessity.

DOSAGE GUIDELINES

• Moderate Hypofractionation (preferred, for all but low-volume M1, including N1):
  o 3Gy x 20 fractions
  o 2.7Gy x 26 fractions
  o 2.5 x 28 fractions

• Ultra-Hypofractionation (for all but N1 and M1):
  o 7.25-8Gy x 5 fractions & 6.1Gy x 7 fractions

• Ultra-Hypofractionation (for low-volume M1):
  o 6Gy x 6 fractions

• Low-volume metastatic disease
  o Per STAMPEDE phase 3 randomized trial,³ 55Gy in 20 fractions (i.e., 2.75Gy x 20) or 6Gy x 6 fractions can be used.

• High-volume metastatic disease (Visceral met, 4 or more bone mets with at least one metastasis beyond the pelvis vertebral column):
  o Based on HORRAD⁴ & STAMPEDE trials no RT to prostate would be medically necessary.
• Proton beam is not an approved treatment option for prostate cancer. Studies comparing proton beam therapy alone to 3-D conformal radiation or IMRT are limited. Overall, studies have not shown clinical outcomes to be superior to conventional radiation therapy.1, 2, 5-8

BACKGROUND
Prostate cancer is diagnosed by biopsy and evaluated (staged) to determine extent of disease (local, regional, or distant metastatic). Both surgery and radiation therapy is used to treat prostate cancers that are organ-confined or extend into tissues adjacent to the prostate. Daily prostate localization can be accomplished with imaging modalities, e.g., ultrasound images, computed tomography (CT) images, or implanted fiducial markers, incorporated into an image guided radiation therapy (IGRT) system.

Patients with very low risk disease should be considered for active surveillance if their life expectancy is less than or equal to 20 years. Active surveillance is as well, recommended for patients with favorable intermediate-risk prostate cancer. Observation is the preferred action for men with low-risk prostate cancer with a life expectancy of less than 10 years. Patients with intermediate risk disease may be considered for short course (4-6 months) of neoadjuvant/concomitant/adjuvant ADT. Patients with high risk disease may be considered for pelvic lymph node irradiation and 2-3 years of neoadjuvant/adjuvant ADT.

POLICY HISTORY

<table>
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| January 2022 | • Changed “Radiation Therapy for Patients with Locally Advanced or Metastatic Prostate (T3b – T4, or any T and N1, disease)” to “Radiation Therapy for Patients with Locally Advanced or N1 Prostate (T3b – T4, or any T and N1, M0 disease)”
• Added Palliative Radiotherapy
  o 30Gy/10FX or
  o 37.5Gy/15FX
• Added Dosage Guidelines section within Treatment Options Requiring Physician Review |
| February 2021 | Deleted: INDICATIONS FOR RADIATION THERAPY AND TREATMENT OPTIONS Changed to: MEDICALLY NECESSARY INDICATIONS FOR RADIATION THERAPY (NCCN, 2021; Morgan et al, 2018):
EBRT/IMRT hypofractionation of 20-28 fractions are recommended to treat localized localized prostate cancer when pelvic nodes are not treated. Other treatment regimens require physician review and clinical documentation that supports medical necessity. |
For Very Low/Low, Intermediate and High/Very High Recurrence Prostate Cancer. The following was deleted:

- *Various fractionation and dose regimens can be considered based on medical necessity.*
- Highly conformal radiation therapy technique 3D-CRT/IMRT with IGRT up to 45 fractions

For Very Low/Low, Intermediate and High/Very High Recurrence Prostate Cancer. The following was updated:

- Highly conformal radiation therapy technique (3D-CRT/IMRT with IGRT). Hypofractionation 20-28 fractions

For Intermediate and High/Very High Recurrence Prostate Cancer. The following was deleted:

- Brachytherapy (LDR/HDR) boost combined with EBRT after 40-50 Gy

For Intermediate and High/Very High Recurrence Prostate Cancer. The following was updated:

- Brachytherapy (LDR/HDR) boost combined with EBRT after 20-28 Fx

Radiation Therapy for Patients with Locally Advanced or Metastatic Prostate (T3b – T4, or any T and N1, M0 disease)

- Deleted: Various fractionation and dose regimens can be considered based on medical necessity.
- Deleted: Highly conformal radiation therapy technique (3D-CRT/IMRT with IGRT). Up to 45 fractions
  - Updated: Highly conformal radiation therapy technique (3D-CRT/IMRT with IGRT). Up to 45 fractions are medically necessary for localized or locally recurrent prostate cancer when pelvic nodes are treated.
  - Deleted: Brachytherapy (LDR/HDR) boost combined with EBRT after 40-50 Gy
  - Updated: Brachytherapy (LDR/HDR) boost combined with EBRT after 20-28 fractions

High Recurrence Risk (Primary Tumor Stage [T] T3a or PSA > 20 ng/ml or Gleason score 8 -10 , or two or more intermediate risk factors) and

Very High Recurrence Risk (Primary Tumor Stage [T] T3b-T4) with Gleason score 8-10 without Metastasis

Under the above sections added update:

- SBRT delivered at five fractions or less at 6.5 Gy per fraction or greater. Appropriate as a standalone radiation modality and NOT as a boost to other conventional methods of radiation treatment.
Post-Prostatectomy guideline heading changed to “Adjuvant Post-Prostatectomy or Salvage Radiation Therapy” to include criteria for Salvage Therapy. Guideline also updated to include extracapular extension. Updated guideline to: Seminal vesicle invasion or extracapsular extension.

**TREATMENT OPTIONS REQUIRING PHYSICIAN REVIEW**

**Added**

- EBRT/IMRT hypofractionation of 20-28 fractions are recommended to treat localized prostate cancer when pelvic nodes are not treated. Other treatment regimens require physician review and clinical documentation that supports medical necessity.

**Added and Updated References**

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<tr>
<td>• Proton Beam: Clarification of Proton Beam Guideline whereby the term <em>localized</em> was removed from the following statement: Proton Beam is not an approved treatment option for <em>localized</em> prostate cancer.</td>
</tr>
<tr>
<td>• Added and updated References</td>
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<tr>
<td>• External Beam Radiation Therapy: Added: ‘SBRT delivered at five fractions or less at 6.5 Gy per fraction or greater. Appropriate as a standalone radiation modality and not as a boost to other conventional methods of radiation treatment’</td>
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ADDITIONAL RESOURCES


8—Prostate Cancer Rad Onc

Reviewed / Approved by NIA Clinical Guideline Committee
GENERAL INFORMATION
It is an expectation that all patients receive care/services from a licensed clinician. All appropriate supporting documentation, including recent pertinent office visit notes, laboratory data, and results of any special testing must be provided. If applicable: All prior relevant imaging results and the reason that alternative imaging cannot be performed must be included in the documentation submitted.

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MEDICALLY NECESSARY INDICATIONS FOR PROTON BEAM THERAPY (Requires Physician Review)

Treatment of the following in children less than 21 years of age
- Primary or benign solid tumors (curative intent; occasional palliative treatment) when sparing of surrounding normal tissues cannot be achieved with photon therapy

Treatment at any age\(^1\)
- Primary hepatocellular tumors treated with hypofractionated regimens
- Spinal tumors (primary or metastatic) where spinal cord has previously been treated with radiation or where the spinal cord tolerance may be exceeded with conventional treatment
- Tumors at the base of skull (chordoma, chondrosarcomas)
- Intraocular melanomas or other ocular tumors
- Patients with genetic syndromes making total volume of radiation minimization crucial, such as, but not limited to NF-1 patients and retinoblastoma patients
- Non-metastatic retroperitoneal sarcomas
- Re-irradiation cases (where cumulative critical structure dose would exceed tolerance dose)
- Malignant and benign primary CNS tumors: Consider proton therapy for patients with good long-term prognosis (grade 3 IDH-mutant tumors\(^2\) and 1p19q codeleted tumors\(^3\)) to better spare uninvolved brain and preserve cognitive function
- Craniospinal RT: To reduce toxicity from CSI in adults, consider the use of IMRT or protons if available (for patients with positive CSF or known metastatic disease)\(^4\)
- Advanced (e.g. T4) and/or unresectable head and neck cancers\(^5\)-\(^16\)

\(^1\) National Imaging Associates, Inc. (NIA) is a subsidiary of Evolent Health LLC.
• Cancers of the paranasal sinuses and other accessory sinuses

OTHER TREATMENT OPTIONS REQUIRING PHYSICIAN REVIEW\textsuperscript{1,17}

For peer review purposes supporting documentation from the radiation oncologist is required and should include the clinical rationale for performing proton beam rather than 3-D conformal or IMRT or SRS.

Proton beam therapy has not been proven to be superior to conventional radiation therapy for all other indications including, but not limited to:

• Prostate cancer
• Breast cancer
• Lung cancer
• Colorectal cancer
• Cervical cancer
• Metastasis
• Gliomas (patients other than long-term prognosis (grade 3 IDH-mutant tumors [1] and 1p19q codeleted tumors))
• Soft tissue sarcoma
• Head and Neck (Non-T4 and resectable)
• Pelvic
• Gastric

BACKGROUND
Proton beam therapy (PBT) is a type of external beam radiotherapy that uses charged particles. These particles have unique characteristics including limited lateral slide, scatter, and tissue in a defined range, going for maximum dose delivery over the last few millimeters of the particles' range. The maximum is called the Bragg peak. Proton beam irradiation when applied to treating cancer, uses different proton energy with Bragg peaks at various steps, enabling dose escalation to the tumor, minimizing excess dose to normal surrounding tissue. Over the years, proton beam irradiation has been applied to treating tumors that require dose escalation to achieve a higher probability of care, as well as tumors requiring increased precision in dose deposition while protecting normal surrounding tissue. Proton therapy has an over 40-year history in treating cancer, yet to date, there have been few studies that show superiority to conventional photon beam irradiation, especially with modern techniques.

POLICY HISTORY

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<tr>
<td>January 2022</td>
<td>• Under “Treatment at any age”</td>
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<tr>
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<td>o Added malignant and benign primary CNS tumors</td>
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- Added craniospinal RT
- Added advanced (e.g., T4) and/or unresectable head and neck cancers
- Added cancers of the paranasal sinuses and other accessory sinuses

- Under “Other Treatment Options Requiring Physician Review”
  - Added Gliomas (patients other than long-term prognosis (grade 3 IDH-mutant tumors [1] and 1p19q codeleted tumors))
  - Added Head and Neck (Non-T4 and resectable)

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**ADDITIONAL RESOURCES**


Reviewed / Approved by NIA Clinical Guideline Committee
GENERAL INFORMATION
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INDICATIONS FOR RADIATION THERAPY

Basal & Squamous Cell Skin Cancer

2D or 3D-CRT EBRT (electron/ photon) are appropriate techniques for treatment of basal squamous cell skin cancer for any of the following: definitive treatment for non-surgical candidates, cancer surgery would be disfiguring, further resection needed post-operative or adjuvant therapy for cancers at risk for recurrence. Fractionation and treatment schedules range from single fraction to 33 fractions. Longer fractionation is associated with improved cosmetic results.

Dosage and Schedule Guidelines

- 30-70Gy to up to 38 fractions

Melanoma

2D or 3D-CRT EBRT (electron/ photon) are appropriate techniques for treatment of Melanoma skin cancer for any of the following: adjuvant treatment after resection of primary site, regional disease following resection of nodes, local recurrent disease, or palliative treatment

A wide range of dosage / fractionation schedules is effective up to 38 fractions

Merkel Cell Carcinoma

2D or 3D-CRT EBRT (electron/ photon) are appropriate techniques for treatment of Merkel Cell Carcinoma skin cancer for any of the following: adjuvant treatment after resection of primary site, regional disease following resection of nodes, local recurrent disease, or palliative treatment

A wide range of dosage / fractionation schedules is effective up to 38 fractions

Cutaneous Lymphoma

Total Skin Electron Beam Therapy (TSEBT) may be utilized to cover the entire cutaneous surface.

- Dosage Guidelines:

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1—Skin Cancer

8-36Gy, 1- 2Gy per fraction, 4-5 days per week, up to 36 fractions. “Shadowed” areas may need to be supplemented with individual electron fields. Individual tumors may be boost with doses of 4-12Gy

TREATMENT OPTIONS REQUIRING PHYSICIAN REVIEW:

Brachytherapy
LDR, HDR, surface or interstitial brachytherapy may be considered where excision or EBRT is contraindicated. Electronic brachytherapy is considered experimental and investigational at this time. 1

Intensity modulated radiation therapy (IMRT)
IMRT is not indicated as a standard treatment option and should not be used routinely for the delivery of radiation therapy for skin cancer. IMRT is strictly defined by the utilization of inverse planning modulation techniques. IMRT may be appropriate for limited circumstances in which radiation therapy is indicated and 3D conformal radiation therapy (3D-CRT) techniques cannot adequately deliver the radiation prescription without exceeding normal tissue radiation tolerance, the delivery is anticipated to contribute to potential late toxicity or tumor volume dose heterogeneity is such that unacceptable hot or cold spots are created. If IMRT is utilized, techniques to account for respiratory motion should be performed.

Clinical rationale and documentation for performing IMRT rather than 2D or 3D-CRT treatment planning and delivery will need to:

• Demonstrate how 3D-CRT isodose planning cannot produce a satisfactory treatment plan (as stated above) via the use of a patient-specific dose volume histograms and isodose plans. 3D-CRT techniques such as step-and-shoot or field-in-field should be considered for the comparison.

• Confirm the IMRT requested will be inversely planned (forward plans or 'field-in-field' plans are not considered IMRT).

• Provide tissue constraints for both the target and affected critical structures.

Proton Beam Radiation Therapy
Proton beam is not an approved treatment option for skin cancer. Proton beam has not been proven superior treatment to conventional radiation therapy.

Stereotactic Body Radiation Therapy (SBRT)
Stereotactic Body Radiation Therapy is not a standard treatment option for the treatment of skin cancer. A peer review is required with a radiation oncologist.

BACKGROUND
There are three main types of skin cancer:
• Basal cell carcinoma (BCC)
• Squamous cell carcinoma (SCC)
• Melanoma

BCC and SCC are the most common forms of skin cancer and are collectively referred to as nonmelanoma skin cancers. Nonmelanoma skin cancer is the most commonly occurring cancer in the United States. BCC is the more common type of the two nonmelanoma types, accounting for about three-quarters of nonmelanoma skin cancers. The incidence of nonmelanoma skin cancer appears to be increasing in some areas of the United States. Incidence rates in the United States have likely been increasing for several years. At least some of this increase may be attributable to increasing skin cancer awareness, resulting in an increase in investigation and biopsy of skin lesions.

Melanoma is a malignant tumor of melanocytes, which are the cells that make the pigment melanin and are derived from the neural crest. Melanomas may arise from mucosal surfaces or at other sites to which neural crest cells migrate, including the uveal tract, although most melanomas arise in the skin.

Skin cancer is the most common malignancy diagnosed in the United States, with 3.5 million cancers diagnosed in 2 million people annually and the incidence increasing over the past four decades. Melanoma represents less than 5% of skin cancers but results in most deaths. Elderly men are at highest risk; however, melanoma is the most common cancer in young adults aged 25 to 29 years and the second most common cancer in those aged 15 to 29 years.

**POLICY HISTORY**

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<tr>
<td>January 2022</td>
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<td>• Added Total Skin Electron Beam Therapy (TSEBT) may be utilized to cover the entire cutaneous surface</td>
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<td>• Added dosage guidelines for TSEBT</td>
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ADDITIONAL RESOURCES


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INDICATIONS FOR RADIATION THERAPY

Limited-Stage SCLC (T1-2, N1-N3 M0)¹
2D or 3D Conformal Radiation Therapy (3DCRT)

**Dosage Guidelines:**
- Up to 39 fractions is medically necessary

Extensive-Stage SCLC (T any, N any, M1a/b)¹
2D or 3D Conformal Radiation Therapy (3DCRT) Radiation therapy to treat symptomatic sites or treatment of cord compression

**Dosage Guidelines:**
- Up to 39 fractions is medically necessary

**Prophylactic cranial irradiation** (PCI) is indicated for Limited and Extensive SCLC.¹ PCI is used to decrease the incidence of central nervous system metastases and prolong survival.
- 2D or 3D Conformal Radiation Therapy (3DCRT)

**Dosage Guidelines**
- 5-15 fractions is medically necessary

TREATMENT OPTIONS REQUIRING PHYSICIAN REVIEW

**Intensity Modulated Radiation Therapy (IMRT)**
IMRT is not indicated as a standard treatment option and should not be used routinely for the delivery of radiation therapy for small cell lung cancer. IMRT may be appropriate for limited circumstances in which radiation therapy is indicated and 3D conformal radiation therapy (3D-CRT) techniques cannot adequately deliver the radiation prescription without exceeding normal tissue radiation tolerance, the delivery is anticipated to contribute to potential late toxicity or

¹ National Imaging Associates, Inc. (NIA) is a subsidiary of Evolent Health LLC.
tumor volume dose heterogeneity is such that unacceptable hot or cold spots are created. If IMRT is utilized, techniques to account for respiratory motion should be performed.

Clinical rationale and documentation for performing IMRT rather than 2D or 3D-CRT treatment planning and delivery will need to:

- Demonstrate how 3D-CRT isodose planning cannot produce a satisfactory treatment plan (as stated above) via the use of a patient-specific dose volume histograms and isodose plans.
- Provide tissue constraints for both the target and affected critical structures.

**Hippocampal Sparing Intensity Modulated Radiation Therapy for PCI**

- The use of hippocampal avoidance with WBRT, using IMRT, lowers the risks of neurocognitive decline (specifically memory and recall), and now supported with level 1 evidence

**Dosage Guidelines**
- 25Gy in 10 fractions is considered medically necessary

**Proton Beam Radiation Therapy**

Proton beam is not an approved treatment option for small cell lung cancer. There are limited clinical studies comparing proton beam therapy to 3-D conformal radiation. Overall, studies have not shown clinical outcomes to be superior to conventional radiation therapy.

**Stereotactic Body Radiation Therapy (SBRT)**

SBRT is approvable for clinical stage I to IIA (T1-2,N0) Small Cell Lung Cancer who are medically inoperable or refuse surgery.

**THE FOLLOWING APPLIES TO CMS (MEDICARE) MEMBERS ONLY:**

For Proton Beam Radiation Therapy refer to Local Coverage Determination (LCD), if applicable.

**BACKGROUND**

The two major types of lung cancer are small cell lung cancer (SCLC) and non-small cell lung cancer (NSCLC). SCLC differs significantly from NSCLC in that most patients with SCLC present with subclinical metastatic disease. Patients with SCLC are divided into those with limited- versus extensive-stage disease. Although limited-stage disease is confined to the ipsilateral hemithorax, a third of these patients have subclinical systemic disease. Extensive-stage disease is defined as disease extending beyond the ipsilateral hemithorax, including positive pleural/pericardial effusion or distant metastases. Systemic chemotherapy is an essential
component of appropriate treatment for all SCLC patients, even those with limited-stage disease.

This guideline outlines methods suitable for the delivery of radiation therapy to treat SCLC. Radiation therapy may be delivered using conventional, accelerated fractionation, hyperfractionated regimens and prophylactic cranial irradiation. Three-dimensional conformal radiation therapy (3D-CRT) is the preferred technique. If image-guided radiation therapy is utilized, techniques to account for respiratory motion should be performed. The goal of this guideline is to guide diagnosis and treatment to the most efficient, comparatively effective, diagnostic and treatment pathway.

SCLC is highly sensitive to initial chemotherapy and radiation therapy; however, a cure is difficult to achieve because SCLC generally has a rapid doubling time, a high growth fraction, and early development of widespread metastases.

The treatment goal in patients with limited-stage disease is to achieve a cure with chemotherapy combined with thoracic radiation therapy. In patients with extensive-stage disease, this combined modality treatment does not improve survival compared with chemotherapy alone, but radiation therapy plays a role in palliation of symptoms. All patients with SCLC require systemic chemotherapy and where radiation therapy is utilized, it should be delivered concurrently with chemotherapy. Patients with both limited- and extensive-stage disease may benefit from prophylactic cranial irradiation (PCI), decreasing the incidence of central nervous system metastases and prolonging survival. Two-dimensional, post lateral fields should be used in PCI treatment.

POLICY HISTORY

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| January 2022 | • Added Hippocampal Sparing Intensity Modulated Radiation Therapy for PCI, including dosage guidelines  
• Updated SBRT as “approvable for clinical stage I to IIA (T1-2,N0) Small Cell Lung Cancer who are medically inoperable or refuse surgery”  
• Deleted “Stereotactic Body Radiation Therapy (SBRT) is not considered a standard form of treatment for SCL cancer. SBRT may be considered medically necessary to treat a previously irradiated field A request for SBRT will require a peer review to make a medical necessity determination.” |
| February 2021 | Guideline Clarification:  
Deleted: Stereotactic Body Radiation Therapy (SBRT) is not considered a standard form of treatment for SCL cancer. Overall, studies have not shown clinical outcomes to be superior to conventional radiation therapy. A request for SBRT will require a peer review to make a medical necessity determination. |
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Stereotactic radiation therapy (SRT) is a method of delivering precise high doses of radiation to small targets, while minimizing radiation-related injury in adjacent normal tissues.\(^1,2\) SRT delivers high doses of radiation in a very short time frame as, between 1 and 5 fractions (entire course not to exceed 5 fractions) and consists of the following types:\(^1\):

- Stereotactic Body Radiotherapy (SBRT) refers to use at any extracranial site consisting of 2-5 fractions
- Stereotactic Cranial Radiotherapy consisting of 2-5 fractions to use at any intracranial site
- Stereotactic radiosurgery (SRS) refers to treatment of any intracranial site consisting of 1 fraction only.

**INDICATIONS FOR STEREOTACTIC RADIATION THERAPY**

Most requests for radiation therapy are addressed by NIA treatment site clinical guidelines. However, there may be requests that are not. For such requests, determinations will be made on a case-by-case basis utilizing the following guidelines (when applicable) but not limited to: National Comprehensive Cancer Network (NCCN), American Society for Radiation Oncology ASTRO (i.e., Model Policies; Evidence-Based Consensus Statement), ACR Appropriateness Criteria, American Society of Clinical Oncology (ASCO) and/or peer reviewed literature.

- Arteriovenous malformation (AVM) of the brain or spine\(^1\)

- Initial or recurrent primary brain tumor (e.g., acoustic neuroma, meningioma, hemangioma, pituitary adenoma, craniopharyngioma, low grade glioma, neoplasm of the pineal gland, glioblastoma multiforme, low-grade astrocytoma, etc.)\(^1\)

- Initial or recurrent brain metastases for patient who has good performance status (ECOG less than 3 or Karnofsky status 40 or greater with expected return to 70 or greater with treatment) and controlled systemic disease (e.g., newly diagnosed, stable systemic disease or reasonable treatment options).\(^1\) Refer to the clinical guideline on Central Nervous System (CNS) metastasis.
• Non-operable spinal tumor (primary, recurrent or metastatic) that is causing compression or intractable pain

• Trigeminal neuralgia that has not responded to other, more conservative, treatments

• Non-Small Cell Lung Cancer and all of the following:
  o Stage I disease; **AND**
  o The lesion cannot be removed surgically either because the tumor location makes removal difficult, the member is not a surgical candidate, or if the patient refuses surgery

• Small Cell Lung Cancer
  o SBRT is approvable for clinical stage I to IIA (T1-2,N0) Small Cell Lung Cancer who are medically inoperable or refuse surgery.

**PHYSICIAN CLINICAL REVIEW REQUIRED**

• Stereotactic Radiation Therapy (SRS/SBRT) has not been proven to be superior to conventional therapy and is not a standard treatment option for the treatment of the following conditions:
  o Other non-central nervous system cancers unless noted above
  o Lung (unless above criteria is met)
  o Other cancers, including but not limited to, breast, colon, liver and pancreas
  o Parkinson’s disease and other movement disorders (e.g., tremors)
  o Epilepsy
  o Chronic pain syndromes
  o Treatment of functional disorders other than trigeminal neuralgia

• Pancreatic Tumors: SBRT is appropriate for pancreatic cancer to treat locally advanced or recurrent disease without evidence of distant metastasis or to treat a previously irradiated field

• **Oligometastatic Disease**
  o Stereotactic Body Radiation Therapy (SBRT) is medically necessary for extracranial oligometastatic disease for an individual with One (1) to Five (5) metastatic lesions when the following criteria are met:
    ▪ Good performance status: ECOG less than 3 or Karnofsky Scale greater than or equal to 70% and stable systemic disease or reasonable systemic treatment options.

• SBRT may be appropriate for patients with tumors arising in or near previously irradiated region to minimize the risk of injury to surrounding normal tissues (Physician Review Required)
## POLICY HISTORY

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| January 2022  | • Added SCLC: SBRT is approvable for clinical stage I to IIA (T1-2, N0) SCLC who are medically inoperable or refuse surgery  
• Clarified “Good performance status” under Oligometastatic disease  
• Under Oligometastatic disease, increased range of metastatic lesions to 1 – 5 (previously 1 – 4) |
| February 2021 | **Deleted:** Stereotactic Body Radiation Therapy (SBRT) is considered medically necessary for the treatment of pancreatic cancer. If requested a physician review is required.  
**Updated:** Pancreatic Tumors (NCCN, 2019) SBRT is is appropriate for pancreatic cancer to treat locally advanced or recurrent disease without evidence of distant metastasis or to treat a previously irradiated field (Physician Review Required)  
Added  
• Oligometastatic Disease: Stereotactic Body Radiation Therapy (SBRT) is medically necessary for extracranial oligometastatic disease for an individual with One (1) to Four (4) metastatic lesions when the following criteria are met: (Cheung P, 2016; Palma 2018)  
  o Good performance status: ECOG less than 3 or Karnofsky Scale greater than or equal to 70% and  
  o Stable systemic disease or reasonable systemic treatment options. |
| February 2020 | • Guideline updated to state that SBRT is medically necessary for pancreatic tumors and patients with tumors previously irradiated, Based on NCCN Guideline Updates  
  o Added: Pancreatic Tumors (Physician Review Required)  
  o Added: SBRT may be appropriate for patients with tumors arising in or near previously irradiated region to minimize the risk of injury to surrounding normal tissues (Physician Review Required) |
| February 2019 | • Added and updated references                                                                                                                                                                          |
REFERENCES


**ADDITIONAL RESOURCES**


Reviewed / Approved by NIA Clinical Guideline Committee
GENERAL INFORMATION
It is an expectation that all patients receive care/services from a licensed clinician. All appropriate supporting documentation, including recent pertinent office visit notes, laboratory data, and results of any special testing must be provided. If applicable: All prior relevant imaging results and the reason that alternative imaging cannot be performed must be included in the documentation submitted.

Disclaimer: National Imaging Associates, Inc. (NIA) authorization policies do not constitute medical advice and are not intended to govern or otherwise influence the practice of medicine. These policies are not meant to supplant your normal procedures, evaluation, diagnosis, treatment and/or care plans for your patients. Your professional judgement must be exercised and followed in all respects with regard to the treatment and care of your patients. These policies apply to all Evolent Health LLC subsidiaries including, but not limited to, National Imaging Associates (“NIA”). The policies constitute only the reimbursement and coverage guidelines of NIA. Coverage for services varies for individual members in accordance with the terms and conditions of applicable Certificates of Coverage, Summary Plan Descriptions, or contracts with governing regulatory agencies. NIA reserves the right to review and update the guidelines at its sole discretion. Notice of such changes, if necessary, shall be provided in accordance with the terms and conditions of provider agreements and any applicable laws or regulations.