

National Imaging Associates, Inc.*

2024 NIA Clinical Guidelines For Medical Necessity Review

RADIATION ONCOLOGY GUIDELINES

Effective January 1, 2024 – December 31, 2024



**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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TABLE OF CONTENTS

RADIATION ONCOLOGY GUIDELINES

2D – 3D CONFORMAL RADIATION THERAPY (CRT), EXTERNAL BEAM RADIATION THERAPY FOR OTHER CANCERS

ANAL CANCER

BONE METASTASES

BRACHYTHERAPY

BREAST CANCER

CERVICAL CANCER

CENTRAL NERVOUS SYSTEM METASTATIC TUMORS

CENTRAL NERVOUS SYSTEM PRIMARY

COLORECTAL CANCER

ENDOMETRIAL CANCER

GASTRIC CANCER

HEAD AND NECK CANCER

HODGKINS LYMPHOMA

HYPERTHERMIA

INTENSITY MODULATED RADIATION THERAPY (IMRT) FOR OTHER CANCERS

INTRAOPERATIVE RADIATION THERAPY (IORT)

METASTATIC DISEASE

NEUTON BEAM THERAPY (NBT)

NON-HODGKIN'S LYMPHOMA

NON-SMALL CELL LUNG CANCER

NON-CANCEROUS CONDITIONS

PANCREATIC CANCER

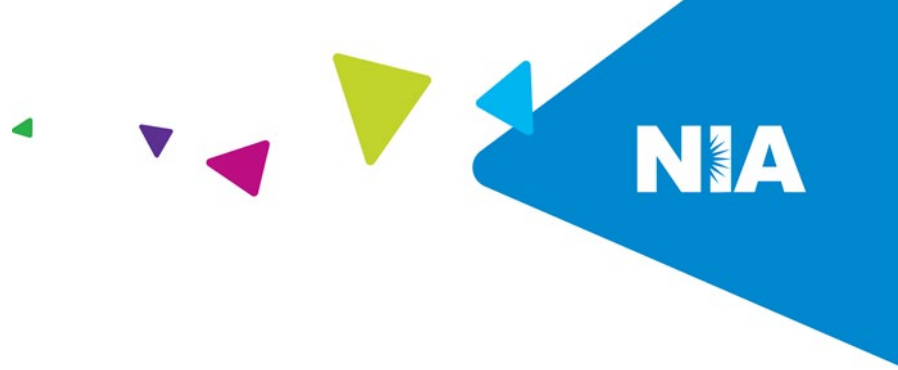
PROSTATE CANCER

PROTON BEAM RADIATION THERAPY

SKIN CANCER

SMALL CELL LUNG CANCER

STEREOTACTIC RADIOTHERAPY (SRS)_STEREOTACTIC BODY RADIATION (SBRT)



*National Imaging Associates, Inc.	
Clinical guideline: 2D – 3D CONFORMAL RADIATION THERAPY (CRT), EXTERNAL BEAM RADIATION THERAPY FOR OTHER CANCERS	Original Date: November 2013
CPT Codes: 77401, 77407, 77412	Last Revised Date: May 2023
Guideline Number: NIA_CG_225	Implementation Date: January 2024

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.*
- *Where a specific clinical indication is not directly addressed in this guideline, medical necessity determination will be made based on widely accepted standard of care criteria. These criteria are supported by evidence-based or peer-reviewed sources such as medical literature, societal guidelines and state/national recommendations.*

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),¹ American Society for Radiation Oncology ASTRO (i.e., Model Policies; Evidence-Based Consensus Statement),² ACR Appropriateness Criteria,³ American Society of Clinical Oncology (ASCO)⁴ 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 will require clinical rationale and will be reviewed on a case-by-case basis.

REFERENCES

1. NCCN guidelines-Treatment by cancer type. National Comprehensive Cancer Network. Updated 2022. Accessed December 27, 2022. https://www.nccn.org/guidelines/category_1
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3. ACR Appropriateness Criteria. American College of Radiology. Updated 2022. Accessed December 27, 2022. <https://acsearch.acr.org/list>
4. ASCO guidelines, tools, & resources. American Society of Clinical Oncology. Updated 2022. Accessed December 27, 2022. <https://www.asco.org/practice-patients/guidelines>

POLICY HISTORY

Date	Summary
May 2023	Under fractions >30 (other cancer sites) removed “may be approvable upon physician review” and added “will be reviewed on a case-by-case basis”
January 2022	No changes



Reviewed / Approved by NIA Clinical Guideline Committee

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*National Imaging Associates, Inc.	
Clinical guidelines: ANAL CANCER	Original Date: June 2013
Radiation Oncology	Last Revised Date: May 2023
Guideline Number: NIA_CG_125	Implementation Date: January 2024

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: 45 Gy – 59.4 Gy in 28 to 33 fractions

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

TREATMENT OPTIONS (to be reviewed on a case-by-case basis)

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. These requests will be reviewed on a case-by-case basis.

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

REFERENCES

1. NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines): Anal Carcinoma Version 2.2022. National Comprehensive Cancer Network (NCCN). Updated September 2, 2022. Accessed December 2, 2022. https://www.nccn.org/professionals/physician_gls/pdf/anal.pdf

POLICY HISTORY

Date	Summary
May 2023	<ul style="list-style-type: none">• References updated• Deleted Additional Resources• Replaced “Treatment Options Requiring Physician Review” with “Treatment Options (to be reviewed on a case-by-case basis)”
January 2022	No significant changes



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*National Imaging Associates, Inc.	
Clinical guidelines BONE METASTASES	Original Date: June 2013
Radiation Oncology	Last Revised Date: May 2023
Guideline Number: NIA_CG_126	Implementation Date: January 2024

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 RADIATION THERAPY¹⁻³

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 (Will be reviewed on a case-by-case basis)

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

Stereotactic Body Radiation Therapy (SBRT)^{4,5}

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:
 - 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.⁴

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.

REFERENCES

1. Lutz S, Balboni T, Jones J, et al. Palliative radiation therapy for bone metastases: Update of an ASTRO Evidence-Based Guideline. *Pract Radiat Oncol*. Jan-Feb 2017;7(1):4-12. doi:10.1016/j.prro.2016.08.001
2. ACR Appropriateness Criteria®: Non-Spine Bone Metastases. American College of Radiology. Updated 2014. Accessed December 6, 2022. <https://acsearch.acr.org/docs/69354/Narrative/>
3. American Academy of Hospice and Palliative Medicine. Five Things Physicians and Patients Should Question: Don't recommend more than a single fraction of palliative radiation for an uncomplicated painful bone metastasis. ABIM Foundation. Updated January 14, 2021. Accessed December 6, 2022. <https://www.choosingwisely.org/clinician-lists/american-academy-hospice-palliative-care-single-fraction-palliative-radiation-for-bone-metastasis/>
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5. American Society for Radiation Oncology. Astro Model Policies: Stereotactic Body Radiation Therapy. American Society for Radiation Oncology (ASTRO). Updated June 2020. Accessed December 21, 2022. <https://www.astro.org/ASTRO/media/ASTRO/Daily%20Practice/PDFs/ASTROSBRTModelPolicy.pdf>

POLICY HISTORY

Date	Summary
May 2023	<ul style="list-style-type: none">• No significant changes• References updated• Deleted Additional Resources• Removed “physician review” language
January 2022	<ul style="list-style-type: none">• 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

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*National Imaging Associates, Inc.	
Clinical guideline: BRACHYTHERAPY (Low Dose Radiation (LDR), High Dose Radiation (HDR), Selective Internal Radiation Therapy (SIRT, Electronic Brachytherapy)	Original Date: November 2013
CPT Codes: LDR: 77761, 77762, 77763, 77778, 77789 HDR: 77767, 77768, 77770, 77771, 77772 Electronic Brachytherapy: 0394T, 0395T	Last Revised Date: May 2023
Guideline Number: NIA_CG_224 - 1	Implementation Date: January 2024

GENERAL INFORMATION

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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 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
- 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.

TREATMENT OPTIONS (WILL BE REVIEWED ON A CASE-BY-CASE BASIS) 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:²⁻⁴
 - 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:⁵
 - Fulminant liver failure (absolute)
 - Considerations/Relative Contraindications:⁵
 - 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.^{6,7}
- Coronary Artery Brachytherapy⁸⁻¹⁴
 - 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
 - All other uses of brachytherapy for coronary arteries are considered investigational
- Plaque brachytherapy is a common form of definitive radiotherapy for uveal melanoma¹⁵⁻¹⁷
 - It is appropriate for patients with tumors ≤ 19 mm in largest basal diameter and ≤ 10 mm in thickness. It may be used selectively in patients with larger tumors
 - It is appropriate both as an upfront therapy after initial diagnosis, or after local recurrence following a prior local therapy
 - Iodine-125 Collaborative Ocular Melanoma Study (COMS) plaques: 85Gy should be prescribed to the apex of the tumor at low dose rate (≥ 0.6 Gy/h). The plaque margin on the tumor border should be ≥ 2 mm when feasible. The exception is for tumors near the optic nerve.
 - Non-COMS Iodine-125, and other radioisotopes (e.g., ruthenium-106, palladium-103, strontium-90, cobalt-60, cesium-131): 60-100Gy may be prescribed at low dose rate to the tumor apex.

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1. American Society for Radiation Oncology. ASTRO model policies: Brachytherapy. American Society for Radiation Oncology (ASTRO). Updated January 25, 2019. Accessed December 6, 2022. <https://www.astro.org/ASTRO/media/ASTRO/Daily%20Practice/PDFs/BrachyModelPolicy.pdf>
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8. The American Brachytherapy Society consensus guidelines for plaque brachytherapy of uveal melanoma and retinoblastoma. *Brachytherapy*. Jan-Feb 2014;13(1):1-14. doi:10.1016/j.brachy.2013.11.008
9. NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines): Melanoma: Cutaneous Version 1.2023. National Comprehensive Cancer Network (NCCN). Updated December 22, 2022. Accessed January 3, 2023. https://www.nccn.org/professionals/physician_gls/pdf/cutaneous_melanoma.pdf

POLICY HISTORY

Date	Summary
May 2023	<ul style="list-style-type: none"> • Added plaque brachytherapy for uveal melanoma • Updated references • Changed heading from “Treatment requiring physician review” to “Treatment options (will be reviewed on a case-by-case basis)” • Removed Additional Resources
January 2022	<ul style="list-style-type: none"> • Added absolute contraindication of fulminant liver failure • Added section on Considerations/Relative Contraindications, stating: <ul style="list-style-type: none"> ○ 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



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*National Imaging Associates, Inc.	
Clinical guidelines: BREAST CANCER	Original Date: March 2011
Radiation Oncology	Last Revised Date: May 2023
Guideline Number: NIA_CG_120	Implementation Date: January 2024

GENERAL INFORMATION

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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^{1,2, 3,4}

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^{1,5}

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 regimen⁵

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

Partial Breast Irradiation^{1,6-11}

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 Guidelines¹

- Appropriate fractionation schemes for APBI are:
 - 30 Gy in 5 fractions once a day, preferred^{7,8}
 - 40 Gy in 15 fractions once a day⁹
 - 34 Gy in 10 BID fractions balloon/interstitial brachytherapy¹⁰
 - 38.5 Gy in 10 BID fractions¹¹

Chest Wall Radiation¹

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 (WILL BE REVIEWED ON A CASE-BY-CASE BASIS)

Intensity modulated radiation therapy (IMRT)^{1,12}

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 review, IMRT can be approved for accelerated partial breast irradiation using 30 Gy in 5 fractions once a day regimen.^{7,8} 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 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)^{6,13-15}

- Electron beam IORT should be restricted to women with invasive cancer considered “suitable” for partial breast irradiation
- Since there is no data on the use of IORT with DCIS, the task force recommended that its use be limited to patients with invasive breast cancer
- Single Fraction Electron-beam IORT is considered medically necessary in accordance with ASTRO guidelines if the following criteria are met (suitable group):
 - Individual is 45 years of age or older with invasive cancer
 - T Stage: T1 (tumor up to 3.5 cm)
 - Clinically node negative
 - Negative surgical margins

- The use of electronic brachytherapy for IORT (such as Intrabeam, Xofigo 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.

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 histopathological 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.

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POLICY HISTORY

Date	Summary
May 2023	<p>Clarified/updated:</p> <p>Intraoperative radiation therapy (IORT)</p> <ul style="list-style-type: none"> • Electron beam IORT should be restricted to women with invasive cancer considered “suitable” for partial breast irradiation • Since there is no data on the use of IORT with DCIS, the task force recommended that its use be limited to patients with invasive breast cancer • Single Fraction Electron-beam IORT is considered medically necessary in accordance with ASTRO guidelines if the following criteria are met (suitable group): <ul style="list-style-type: none"> ○ Individual is 45 years of age or older with invasive cancer ○ T Stage: T1 (tumor up to 3.5 cm) ○ Clinically node negative ○ Negative surgical margins • Updated references • Deleted Additional Resources • Removed “physician review” language
January 2022	<p>Whole Breast Radiation:</p> <ul style="list-style-type: none"> • Added ultra-hypofractionated dosage guidelines <p>Partial Breast Irradiation:</p> <ul style="list-style-type: none"> • Updated dosage guidelines • Updated criteria for indications for patients (Suitable Group): <ul style="list-style-type: none"> ○ Removed No use of adjuvant chemotherapy ○ Added Invasive Ductal Carcinoma or Low Grade-Intermediate Grade Ductal Carcinoma in Situ (DCIS) ○ Added No or minimal lymphovascular invasion ○ Added Positive Estrogen Receptor ○ Clarified Negative surgical margins by adding “(more than or equal to 2mm for Invasive Ductal Carcinoma, more than or equal to 3mm for DCIS)” ○ 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) <p>Intensity modulated radiation therapy (IMRT)</p> <ul style="list-style-type: none"> • 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.”

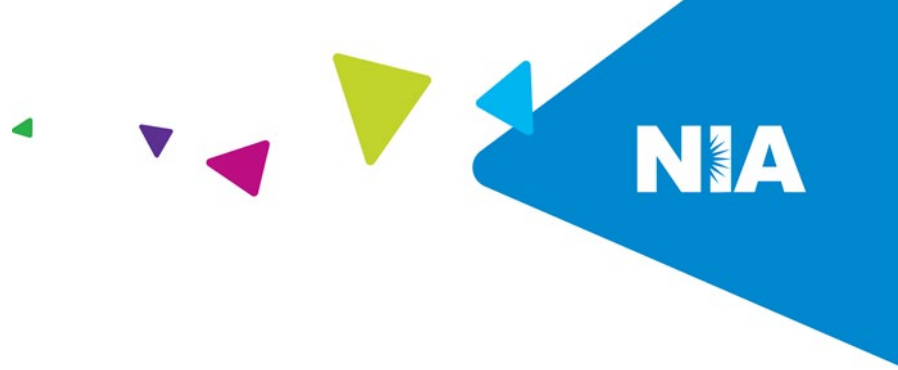


	<p>Intraoperative radiation therapy (IORT)</p> <ul style="list-style-type: none">• Changed to “Individual is 45 years of age or older with invasive cancer” (previously was 50 years of age or older with invasive cancer)• Clarified TStage: Tis or T1 by adding “(tumor up to 3.5 cm)”
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Reviewed / Approved by NIA Clinical Guideline Committee

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*National Imaging Associates, Inc.	
Clinical guideline CERVICAL CANCER	Original Date: June 2013
Radiation Oncology	Last Revised Date: May 2023
Guideline Number: NIA_CG_127	Implementation Date: January 2024

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.*
- *Where a specific clinical indication is not directly addressed in this guideline, medical necessity determination will be made based on widely accepted standard of care criteria. These criteria are supported by evidence-based or peer-reviewed sources such as medical literature, societal guidelines and state/national recommendations.*

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-III A – 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 para-aortic 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 10-15 Gy. IMRT is approvable when the para-aortic nodes are being treated.

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 (45-50 Gy; 28 fx max) +/-concurrent chemotherapy

- Patients with positive nodes, positive margins and/or parametrial invasion –
 - Pelvic 2D/3D-CRT/IMRT (45-50 Gy; 28 fx max) + concurrent chemotherapy
 - Pelvic 2D/3D-CRT/IMRT (45-50 Gy; 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 10-15 Gy. 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
 - Possible Brachytherapy (LDR or HDR) for centralized disease < 2cm Tumor directed 2D/3D-CRT +/- chemotherapy if noncentral disease
 - External Beam Radiation Therapy

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

Stereotactic Body Radiation Therapy (SBRT) Stereotactic Body Radiation Therapy is not a standard treatment option for the treatment of cervical cancer.

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.

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POLICY HISTORY:

Date	Summary
May 2023	Under Definitive/Preoperative Radiation Therapy <ul style="list-style-type: none">• Added: IMRT is approvable when the para-aortic nodes are being treated• Revised: Pelvic radiation therapy from Stage IB2-IIA to Stage Stage IB2-IIIA• Deleted Additional Resources
January 2022	<ul style="list-style-type: none">• <i>Added IMRT to Postoperative (Adjuvant) Radiation Therapy</i>• <i>Moved the following from Local/Regional Recurrence section to Postoperative (Adjuvant) Radiation Therapy section</i><ul style="list-style-type: none">○ <i>Grossly involved unresected nodes may be evaluated for boosting with an additional 10-15Gy</i>○ <i>Unless otherwise indicated, standard radiation fractionation consists of 1.8 Gy to 2.0 Gy per day</i>• <i>Under Treatment Options Requiring Additional Clinical Review:</i><ul style="list-style-type: none">○ <i>Added IMRT for Post-operation Radiation</i>○ <i>Clarified that SBRT can be given for limited disease in the re-irradiation setting</i>



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*National Imaging Associates, Inc.	
Clinical guideline CENTRAL NERVOUS SYSTEM - METASTASES	Original Date: June 2013
Radiation Oncology	Last Revised Date: May 2023
Guideline Number: NIA_CG_128-1	Implementation Date: January 2024

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.*
- *Where a specific clinical indication is not directly addressed in this guideline, medical necessity determination will be made based on widely accepted standard of care criteria. These criteria are supported by evidence-based or peer-reviewed sources such as medical literature, societal guidelines and state/national recommendations.*

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

Metastatic Brain Tumors¹⁻⁴

- For patients with favorable prognosis and limited brain metastases, routine adjuvant WBRT added to SRS is not recommended³
- For patients with favorable prognosis (estimated using a validated brain metastasis prognostic index) and brain metastases ineligible for surgery and/or SRS, WBRT (e.g., 3000cGy in 10 fractions) is recommended as primary treatment³
- SRS, WBRT, and the combination of SRS plus WBRT are all reasonable options for patients with more than four unresected brain metastases and better performance status (e.g., KPS > 70). SRS may be preferred for patients with better prognosis or where systemic therapy that is known to be active in the CNS is available²
- Whole Brain Radiation Therapy (WBRT) with 2D or 3D Conformal treatment is appropriate for treatment Metastatic Brain Tumors - Up to 15 Fractions
- Stereotactic Radiosurgery / Fractionated Stereotactic Radiosurgery (SRS/FSRT) up to 5 fractions is medically necessary if all the following criteria are met (excluding small-cell carcinoma):
 - 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
 - For patients with an ECOG performance status of 0-2 and 5-10 intact brain metastases, SRS is conditionally recommended³
- Intensity Modulated Radiation Therapy will be reviewed on a case-by-case
 - IMRT for partial brain irradiation is approvable

Post Metastasis Resection¹

- For patients with intact brain metastases measuring > 4 cm in diameter, surgery is conditionally recommended³
- SRS, WBRT, and the combination of SRS plus WBRT are all reasonable options for patients with more than two resected brain metastases and better performance status (e.g., KPS ≥ 70). SRS may be preferred for patients with better prognosis or where systemic therapy that is known to be active in the CNS is available²
- For patients with resected brain metastases and limited additional brain metastases, SRS is recommended over WBRT to preserve neurocognitive function and patient-reported QoL³
- Stereotactic Radiosurgery/ Fractionated Stereotactic Radiosurgery (SRS/FSRT) post metastasis resection (up to 5 fractions)
 - SRS alone should be offered to patients with one to two resected brain metastases if the surgical cavity can be safely treated and considering the extent of remaining intracranial disease²

Dose Guidelines

- WBRT 20-40Gy (20 fractions maximum)

Pre-Metastasis Resection

- For patients whose brain metastasis is planned for resection, preoperative SRS is conditionally recommended as a potential alternative to postoperative SRS³

Palliative

- For patients with poor prognosis and brain metastases, early introduction of palliative care for symptom management and caregiver support are recommended³
- For patients with poor predicated prognosis and with symptomatic brain metastases, standard WBRT of 20Gy in 5 fractions is a reasonable option
- Radiation therapy should not be offered to patients with asymptomatic brain metastases who have³:
 - Performance status Karnofsky Performance Status (KPS) < 50 or less, or
 - Performance status KPS < 70 and no systemic therapy options.

Metastatic Spine Tumors¹

- 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
- Stereotactic radiotherapy may be appropriate for Oligometastatic Disease⁴:
 - One (1) to five (5) metastatic lesions and
 - 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.

TREATMENT OPTIONS (WILL BE REVIEWED ON A CASE-BY-CASE BASIS)

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, 5-7}

- Hippocampal sparing whole brain IMRT (plus memantine) 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, lymphoma or unknown
- Dosage Guidelines
 - Standard doses vary between 30Gy and 37.5Gy in 10-15 fractions.

INDICATIONS FOR PROTON BEAM THERAPY

- Proton Beam Radiation Therapy for central nervous system lesions adjacent to the brain stem, spinal cord, or optic nerve will be reviewed on a case-by-case basis. A treatment plan with a comparison to conventional IMRT/SRS may be required
- Requests for Proton Beam Radiation Therapy beyond the indications listed above will be reviewed on a case-by-case basis.

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 will be reviewed on a case-by-case basis to determine medical necessity.

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.

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POLICY HISTORY

Date	Summary
May 2023	<ul style="list-style-type: none"> • Clarified/updated Metastatic Brain Tumors • Clarified updated Post Metastasis Resection • Added Pre-Metastasis Resection • Added Palliative section • Clarified/updated Metastatic Spine Tumors • Clarified/updated Hippocampal Sparing Whole Brain IMRT • Removed Stereotactic Radiosurgery (SRS) or Fractionated Stereotactic Radiosurgery (FSRT) • Removed Proton Beam Radiation Therapy (Added to INDICATIONS FOR PROTON BEAM THERAPY) • Removed Small Cell from: “Whose primary histology is not germ cell, lymphoma or unknown” under hippocampal avoidance • Updated references • Deleted Additional Resources • Removed “physician review” language
January 2022	<ul style="list-style-type: none"> • Under Hippocampal Sparing Whole Brain Intensity Modulated Radiation Therapy: <ul style="list-style-type: none"> ○ Clarified that IMRT is considered medically necessary for metastatic brain lesions in individuals with all of the following: <ul style="list-style-type: none"> ▪ 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 ○ Added Dosage Guidelines



Reviewed / Approved by NIA Clinical Guideline Committee:

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*National Imaging Associates, Inc.	
Clinical guideline CENTRAL NERVOUS SYSTEM – PRIMARY NEOPLASM AND METASTATIC TUMORS	Original Date: June 2013
Radiation Oncology	Last Revised Date: May 2023
Guideline Number: NIA_CG_128	Implementation Date: January 2024

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.*
- *Where a specific clinical indication is not directly addressed in this guideline, medical necessity determination will be made based on widely accepted standard of care criteria. These criteria are supported by evidence-based or peer-reviewed sources such as medical literature, societal guidelines and state/national recommendations.*

INDICATIONS FOR RADIATION THERAPY FOR PRIMARY CNS NEOPLASMS

3D, IMRT and SRS/FSRT techniques may be used as appropriate, depending on the tumor location and stage of disease.

Gliomas^{1,2}

- **Oligodendroglioma, IDH-mutant, and 1p/19q codeleted**
 - For patients with oligodendroglioma, IDH-mutant, 1p/19q codeleted, WHO grade 2, < 4-6 cm tumor, with gross total resection (defined as < 1 cm residual tumor on MRI) and age < 40 y, close surveillance alone is recommended
 - For patients with oligodendroglioma, IDH-mutant, 1p/19q codeleted, WHO grade 2, with high-risk features (subtotal resection, age ≥ 40 y, tumor size ≥ 4-6 cm, tumor crosses midline, refractory seizures, or presurgical neurologic symptoms from tumor), either RT with sequential chemotherapy or RT with concurrent/sequential chemotherapy is conditionally recommended
 - For patients with oligodendroglioma, IDH-mutant, 1p/19q codeleted, WHO grade 3, with any extent of surgery, either RT with sequential chemotherapy or RT with concurrent/sequential chemotherapy is recommended
- **Astrocytoma, IDH-mutant**

- For patients with astrocytoma, IDH-mutant, WHO grade 2, < 4-6 cm tumor, with gross total resection (defined as < 1 cm residual tumor on MRI), and age < 40 y, close surveillance alone is conditionally recommended
- For patients with astrocytoma, IDH-mutant, WHO grade 2, with high-risk features (subtotal resection, age ≥ 40 y, tumor size ≥ 4-6 cm, tumor crosses midline, refractory seizures, or presurgical neurologic symptoms from tumor), either RT with sequential chemotherapy or RT with concurrent/sequential chemotherapy is conditionally recommended
- For patients with astrocytoma, IDH-mutant, WHO grade 3, with any extent of surgery, either RT with sequential chemotherapy or RT with concurrent/sequential chemotherapy is recommended

Dosage Guidelines

- Oligodendroglioma, IDH-mutant, 1p/19q codeleted
 - WHO grade 2: 45-54Gy up to 30 fractions
 - WHO grade 3: 59.4cGy up to 33 fractions
- Astrocytoma, IDH-mutant
 - WHO grade 2: 45-54Gy up to 30 fractions
 - WHO grade 3: 59.4-60Gy up to 33 fractions
- High Grade Tumors – Grade III or IV
 - Post-operative/biopsy: up to 33 fractions
 - In poorly performing patients or elderly patients, a hypofractionated accelerated course over 2–4 weeks should be considered
 - 34Gy/10 fractions of 3D-CRT
 - 40.05Gy/15 fractions of 3D-CRT
 - 25Gy/5 fractions of 3D-CRT
- IDH-mutant WHO grade 2/3 Diffuse Glioma
 - Consider proton therapy
- Recurrence
 - Low Grade: Up to 33 fractions
 - High Grade: 35Gy in 10 fractions of 3D-CRT
 - SRS/FSRT: up to 5 fractions
 - Consider reirradiation on select cases. Proton Beam Therapy may be considered.

Ependymoma – High (Anaplastic) or Low Grade¹

- Brain and/or spine: up to 33 fractions

Meningiomas¹

- WHO Grade 1
 - 50–50.4Gy up to 28 fractions
 - SRS/FSRT (up to 5 fractions)
- WHO Grade 2
 - 54-60Gy up to 30 fractions
 - SRS/FSRT (up to 5 fractions)
- WHO Grade 3
 - 59.4–60Gy up to 30 fractions
 - SRS/FSRT (up to 5 fractions)

CNS Lymphoma¹

- Complete response to chemotherapy
 - Low-dose WBRT should be limited to 23.4Gy (up to 13 fractions of 3D-CRT)
- Less than complete response to chemotherapy, or not candidates for chemotherapy
 - WBRT up to 20 fractions with or without Limited field boost 3D/IMRT (up to 25 fractions)

Medulloblastoma/Supratentorial PNET (Adult)¹

Craniospinal radiation with brain primary site boost – 3D-CRT/IMRT/PBT up to 31 fractions

Primary Spinal Cord¹

- 3D-CRT/IMRT (up to 28 fractions)
 - Tumor below conus medullaris 3D-CRT/IMRT (up to 33 fractions)
- SRS/FSRT – (up to 5 fractions)

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)
- 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 2 and 3 IDH-mutant diffuse glioma and 1p19q codeleted tumors)
- 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)³

Requests for Proton Beam Radiation Therapy beyond the indications listed above will be reviewed on a case-by-case basis 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

Stereotactic Radiosurgery (SRS) or Fractionated Radiosurgery (FSRT)^{1, 4}

- If SRS or FSRT is not indicated as a medically necessary treatment option, a peer review will be required.

Proton Beam Radiation Therapy^{3, 5}

Requests for Proton Beam Radiation Therapy will be reviewed on a case-by-case basis (See Proton Beam Guideline).

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)
- 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 2 and 3 IDH-mutant diffuse glioma and 1p19q codeleted tumors)
- 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)³

Requests for Proton Beam Radiation Therapy beyond the indications listed above will be reviewed on a case-by-case bases as outlined below to determine medical necessity.

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.

REFERENCES

1. NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines): Central Nervous System Cancers Version 2.2022. National Comprehensive Cancer Network (NCCN). Updated September 29, 2022. Accessed December 13, 2022. https://www.nccn.org/professionals/physician_gls/pdf/cns.pdf
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POLICY HISTORY

Date	Summary
May 2023	<ul style="list-style-type: none"> • Updated/Clarified Gliomas, ependymoma, meningioma, CNS lymphoma, and primary spinal cord • Removed Hippocampal Sparing Whole Brain Intensity Modulated Radiation Therapy • Added indications for proton beam therapy • Deleted Additional Resources • Removed “physician review” language
January 2022	<ul style="list-style-type: none"> • Under Indications for Proton Beam Therapy (Treatment at any age) <ul style="list-style-type: none"> ○ 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) ○ 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: <ul style="list-style-type: none"> ○ 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 • Added: Dosage Guidelines under Hippocampal Sparing Whole Brain Intensity Modulated Radiation Therapy



Reviewed / Approved by NIA Clinical Guideline Committee:

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*National Imaging Associates, Inc.	
Clinical guidelines: COLORECTAL CANCER	Original Date: March 2011
Radiation Oncology	Last Revised Date: May 2023
Guideline Number: NIA_CG_121	Implementation Date: January 2024

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.*
- *Where a specific clinical indication is not directly addressed in this guideline, medical necessity determination will be made based on widely accepted standard of care criteria. These criteria are supported by evidence-based or peer-reviewed sources such as medical literature, societal guidelines and state/national recommendations.*

INDICATIONS FOR RADIATION THERAPY

- **Colon Cancer**
 - Radiation therapy is indicated for T4 tumors with penetration/perforation, intermediate/positive margins, patients with recurrent disease, 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 option¹
 - 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 such as re-irradiation of previously treated patients with recurrence or unique anatomical situations where IMRT facilitates the delivery of recommended target volume doses while respecting accepted normal tissue dose-volume constraints (e.g., coverage of external iliac or inguinal nodes).¹ (Will be reviewed on a case-by-case basis)

- 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 resection²
 - 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 tumors²
 - Short-Course radiation therapy (25Gy in 5 fractions) can also be considered for pre-operative radiation
 - 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 chemotherapy²
 - IMRT is not indicated as a standard treatment option and should be reserved for unique situations such as re-irradiation of previously treated patients with recurrence, or in unique anatomical situations (e.g., coverage of external iliac or inguinal lymph nodes in low-lying rectal tumors).² (Will be reviewed on a case-by-case basis)
 - Proton beam is not an approved treatment option for colorectal cancer.

TREATMENT OPTIONS TO BE REVIEWED ON A CASE-BY-CASE BASIS

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.

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.

REFERENCES

1. NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines): Colon Cancer Version 2.2022. National Comprehensive Cancer Network (NCCN). Updated October 17, 2022. Accessed December 2, 2022. https://www.nccn.org/professionals/physician_gls/pdf/colon.pdf
2. NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines): Rectal Cancer Version 3.2022. National Comprehensive Cancer Network (NCCN). Updated October 27, 2022. Accessed December 2, 2022. https://www.nccn.org/professionals/physician_gls/pdf/rectal.pdf

POLICY HISTORY

Date	Summary
May 2023	<ul style="list-style-type: none"> • Removed: 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. • Added under colon cancer: unique anatomical situations where IMRT facilitates the delivery of recommended target volume doses while respecting accepted normal tissue dose-volume constraints (e.g., coverage of external iliac or inguinal nodes). • Added under colon cancer: Patients with recurrent disease • Added under rectal cancer: (e.g., coverage of external iliac or inguinal lymph nodes in low-lying rectal tumors) • Added under rectal cancer: Short-course radiation therapy (25Gy in fractions) can also be considered for pre-operative radiation • Deleted Additional Resources • Removed “physician review” language
January 2022	<ul style="list-style-type: none"> • Added: 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.



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*National Imaging Associates, Inc.	
Clinical guidelines ENDOMETRIAL CANCER	Original Date: June 2013
Radiation Oncology	Last Revised Date: May 2023
Guideline Number: NIA_CG_129	Implementation Date: January 2024

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.*
- *Where a specific clinical indication is not directly addressed in this guideline, medical necessity determination will be made based on widely accepted standard of care criteria. These criteria are supported by evidence-based or peer-reviewed sources such as medical literature, societal guidelines and state/national recommendations.*

INDICATIONS FOR RADIATION THERAPY AND TREATMENT OPTIONS

- Intermediate-risk factors include age \geq 60 years, and focal LVSI
- High-risk factors include substantial LVSI, especially without surgical nodal staging
- High-risk histologies include serous carcinoma, clear cell carcinoma, carcinosarcoma, mixed histology carcinoma, dedifferentiated carcinoma, or undifferentiated carcinoma
- For patients with FIGO stage IA grade 1 or 2 endometrioid carcinoma without intermediate- or high-risk factors, adjuvant RT is not recommended
- For patients who have undergone hysterectomy and pelvic nodal assessment with isolated tumor cells present, it is conditionally recommended that uterine risk factors be used to guide adjuvant therapy¹
- For patients who have undergone hysterectomy and pelvic nodal assessment with nodal micrometastases or macrometastases (FIGO stage IIIC), adjuvant therapy is recommended¹
- For patients with endometrial cancer considering adjuvant therapy, molecular testing is recommended¹
 - Implementation remarks:
 - Immunohistochemistry is needed to assess for mutations in mismatch repair and TP53 genes
 - POLE sequencing can be used to identify hypermutated tumors

- **Molecular classification unknown²**
 - Low Risk group: no adjuvant treatment is recommended
 - Stage IA endometrioid + low-grade + LVSI negative or focal
 - Intermediate Risk group: Adjuvant brachytherapy can be recommended, Omission of adjuvant brachytherapy can be considered (III, C), especially for patients aged < 60
 - Stage IB endometrioid + low-grade + LVSI negative or focal
 - Stage IA endometrioid + high-grade + LVSI negative or focal
 - Stage IA non-endometrioid (serous, clear cell, undifferentiated carcinoma, carcinosarcoma, mixed) without myometrial invasion
 - High–intermediate Risk group: pN0 after lymph node staging adjuvant brachytherapy can be recommended, EBRT can be considered for substantial LVSI and for stage II cN0/pNx (lymph node staging not performed), adjuvant EBRT is recommended, especially for substantial LVSI and/or for stage II, adjuvant brachytherapy alone can be considered for high-grade LVSI negative and for stage II grade 1 endometrioid carcinomas (II, B)
 - Stage I endometrioid + substantial LVSI regardless of grade and depth of invasion
 - Stage IB endometrioid high-grade regardless of LVSI status
 - Stage II
 - High Risk group: EBRT with concurrent and adjuvant chemotherapy (I, A) or alternatively sequential chemotherapy and radiotherapy is recommended, Carcinosarcomas should be treated as high-risk carcinomas (not as sarcomas)
 - Stage III–IVA with no residual disease
 - Stage I–IVA non-endometrioid (serous, clear cell, undifferentiated carcinoma, carcinosarcoma, mixed) with myometrial invasion, and with no residual disease
 - Advanced metastatic: Advanced metastatic: Unresectable primary tumor due to local extent of disease: EBRT should be delivered to pelvis and para-aortic nodes with dose escalation to involved nodes using an integrated or sequential boost, residual pelvic disease (positive resection margin, vaginal disease, pelvic side wall disease): an individualized approach with either radiotherapy or chemotherapy or a combination of both modalities should be considered by a multi-disciplinary team
 - Stage III–IVA with residual disease
 - Stage IVB
- **Molecular classification known²:**
 - Low Risk group: no adjuvant treatment is recommended
 - Stage I–II POLEmut endometrial carcinoma, no residual disease
 - Stage IA MMRd/NSMP endometrioid carcinoma + low-grade† + LVSI negative or focal

- Intermediate Risk group: Adjuvant brachytherapy can be recommended, Omission of adjuvant brachytherapy can be considered (III, C), especially for patients aged < 60
 - Stage IB MMRd/NSMP endometrioid carcinoma + low-grade + LVSI negative or focal
 - Stage IA MMRd/NSMP endometrioid carcinoma + high-grade + LVSI negative or focal
 - Stage IA p53abn and/or non-endometrioid (serous, clear cell, undifferentiated carcinoma, carcinosarcoma, mixed) without myometrial invasion
- High–intermediate Risk group: pN0 after lymph node staging adjuvant brachytherapy can be recommended, EBRT can be considered for substantial LVSI and for stage II cN0/pNx (lymph node staging not performed), adjuvant EBRT is recommended, especially for substantial LVSI and/or for stage II, adjuvant brachytherapy alone can be considered for high-grade LVSI negative and for stage II grade 1 endometrioid carcinomas (II, B)
 - Stage I MMRd/NSMP endometrioid carcinoma + substantial LVSI regardless of grade and depth of invasion
 - Stage IB MMRd/NSMP endometrioid carcinoma high-grade‡ regardless of LVSI status
 - Stage II MMRd/NSMP endometrioid carcinoma
- High Risk group: EBRT with concurrent and adjuvant chemotherapy (I, A) or alternatively sequential chemotherapy and radiotherapy is recommended, Carcinosarcomas should be treated as high-risk carcinomas (not as sarcomas)
 - Stage III–IVA MMRd/NSMP endometrioid carcinoma with no residual disease
 - Stage I–IVA p53abn endometrial carcinoma with myometrial invasion, with no residual disease
 - Stage I–IVA NSMP/MMRd serous, undifferentiated carcinoma, carcinosarcoma with myometrial invasion, with no residual disease
- Advanced metastatic: Unresectable primary tumor due to local extent of disease: EBRT should be delivered to pelvis and para-aortic nodes with dose escalation to involved nodes using an integrated or sequential boost, Residual pelvic disease (positive resection margin, vaginal disease, pelvic side wall disease): an individualized approach with either radiotherapy or chemotherapy or a combination of both modalities should be considered by a multi-disciplinary team
 - Stage III–IVA with residual disease of any molecular type
 - Stage IVB of any molecular type
- **Locally Advanced²**: Per GOG 2058 study, routine pelvic radiotherapy for locally advanced endometrial cancer, has no benefit in disease-free survival when chemoradiation was compared to chemotherapy alone. Therefore, it is reasonable to offer HDR alone³

Post-operative^{4,1}

- Brachytherapy Only (HDR or LDR, 6fx maximum⁵)
 - Stage IA – with adverse risk factors
 - Stage IA – without risk factors (Grade 3)
 - Stage IB (Grades 1, and 2)
- External Beam Radiation Therapy Only (2D, 3D-CRT, 45-50.4 Gy, 28fx maximum) including no pelvic nodal assessment¹
 - Stage IA – with adverse risk factors (Grades G2, 3)
 - Stage IB – without adverse risk factors (Grade G3)
 - Stage IB – with risk factors
 - Stage II (Grades G1, 2, 3)
 - Stage III
 - Stage IVA
- External Beam (2D, 3D-CRT, 45-50.4 Gy, 28fx maximum) and Brachytherapy (HDR or LDR, 6fx maximum⁵ including positive surgical margins¹)
 - 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, 6fx maximum⁵)
 - Stage I & II
- External Beam Radiation Therapy Only (2D, 3D-CRT, 45-50 Gy, 28fx maximum)
 - All Stages
- External Beam (2D, 3D-CRT, 45-50.4 Gy) and Brachytherapy (HDR or LDR, 6fx maximum⁵)
 - All Stages

Note:

- *Unless otherwise indicated, standard radiation fractionation consists of 1.8 Gy to 2.0 Gy per day.*
- *For gross nodal disease, consider boost to 60–65 Gy while respecting normal tissue constraints.*

Palliative

- Up to 10fx

- Hypofractionated Two Week Short-Course Radiotherapy vs. Monthly Single Fraction Palliative Pelvic Radiation in Advanced Gynecologic Cancers, add this fractionation as an option

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.⁴ 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 IMRT¹

- 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. This is supported by a randomized phase III study (NRG Oncology's RTOG 1203)⁶. For gross nodal disease, consider boost to 60-65Gy while respecting normal tissue constraints.⁴
- When para-aortic nodes are being treated

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.⁴

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.⁴ A review of the pathology will determine whether the tumors are of epithelial origin (endometrioid, papillary serous, 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.⁷

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.⁸

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POLICY HISTORY

Date	Summary
May 2023	<ul style="list-style-type: none">• Updated/Clarified: INDICATIONS FOR RADIATION THERAPY AND TREATMENT OPTIONS• Updated/Clarified post-operative, inoperable/preoperative, palliative• Added <i>Note</i>:<ul style="list-style-type: none">○ <i>For gross nodal disease, consider boost to 60–65 Gy while respecting normal tissue constraints.</i>• Deleted additional resources
January 2022	<ul style="list-style-type: none">• Under Post-operative, changed external beam to 50.4 Gy for combination external beam and brachytherapy• Added Post-Operative IMRT under Treatment Options Requiring Additional Clinical Review

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*National Imaging Associates, Inc.	
Clinical guidelines: GASTRIC CANCER	Original Date: June 2013
Radiation Oncology	Last Revised Date: May 2023
Guideline Number: NIA_CG_130	Implementation Date: January 2024

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.*
- *Where a specific clinical indication is not directly addressed in this guideline, medical necessity determination will be made based on widely accepted standard of care criteria. These criteria are supported by evidence-based or peer-reviewed sources such as medical literature, societal guidelines and state/national recommendations.*

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

Dosage Guidelines:

- 45-50.4 Gy up to 28 fractions
- Higher doses may be used for positive surgical margins in selected cases as a boost to that area.

TREATMENT OPTIONS TO BE REVIEWED ON A CASE-BY-CASE BASIS

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:

- 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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POLICY HISTORY

Date	Summary
May 2023	<ul style="list-style-type: none">• Added to dosage guidelines: Higher doses may be used for positive surgical margins in selected cases as a boost to that area• Deleted Additional Resources• Heading changed from “Treatment Options Requiring Physician Review” to “Treatment Options to be reviewed on a case-by-case basis”
January 2022	No significant changes

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*National Imaging Associates, Inc.	
Clinical guidelines HEAD AND NECK CANCER	Original Date: June 2013
Radiation Oncology	Last Revised Date: May 2023
Guideline Number: NIA_CG_131	Implementation Date: January 2024

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.*
- *Where a specific clinical indication is not directly addressed in this guideline, medical necessity determination will be made based on widely accepted standard of care criteria. These criteria are supported by evidence-based or peer-reviewed sources such as medical literature, societal guidelines and state/national recommendations.*

INDICATIONS FOR RADIATION THERAPY

2D, 3D, IMRT and Brachytherapy techniques may be used as appropriate, depending on the tumor location and stage of disease. ¹ Brachytherapy, where appropriate, may be utilized as a boost for 2D, 3D or IMRT courses of radiation therapy.

- Pre-operative radiation therapy
 - 2D/3D/IMRT – up to 35 fractions
- Definitive radiation therapy with or without concurrent chemotherapy
 - 2D/3D/IMRT – up to 42 fractions
 - Hyperfractionation - 81.6 Gy, 1.2 Gy per fraction BID (up to 68 fractions)
 - GRID radiation therapy uses a special block which turns a conventional radiation photon beam into multiple pencil beams. By using this block all the surrounding tissues would be blocked and radiation would be delivered to the GTV/tumor only. This block enables radiation oncologists to deliver high doses of radiation therapy (equivalent to SBRT doses) in one fraction. These treatments would be delivered sequentially, therefore, the total number of fractions. The only technique that would not be approvable would be SBRT because SBRT cannot be combined with any other form of radiation therapy.

- Post-operative radiation therapy (up to 40 fractions)
 - Presence of adverse factors
 - Oral cavity – T1-2, N0 with one positive node without adverse features
 - 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

P16+ Oropharyngeal Cancer

Due to better prognosis, staging of these cancers is different from P16-negative ones (16). De-escalation studies support less intensive treatments including lower doses of radiation therapy.

TREATMENT OPTIONS REQUIRING TO BE REVIEWED ON A CASE-BY-CASE BASIS 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

Proton Beam Radiation Therapy²

Proton beam is not a standard treatment option for head and neck cancer and should not be used routinely. Medical necessity will be determined on a case-by-case basis.

- Re-irradiation up to 34 fractions may be indicated if no metastatic disease present
- Advanced (e.g., T4) and/or unresectable head and neck cancers³⁻¹⁴
- 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.¹⁵ 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.¹ 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.¹ Multidisciplinary management is recommended to best achieve tumor control while reducing toxicity.¹⁵ 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.¹ 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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POLICY HISTORY

Date	Summary
May 2023	<p>Added the following under Post-operative Radiation Therapy</p> <ul style="list-style-type: none"> • Oral cavity – T1-2, N0 with one positive node without adverse features <p>Added the following:</p> <ul style="list-style-type: none"> • P16+ Oropharyngeal Cancer Due to better prognosis, staging of these cancers is different from P16-negative ones (16). De-escalation studies support less intensive treatments including lower doses of radiation therapy. • Added the following to Definitive radiation therapy: GRID radiation therapy uses a special block which turns a conventional radiation photon beam into multiple pencil beams. By using this block all the surrounding tissues would be blocked and radiation would be delivered to the GTV/tumor only. This block enables radiation oncologists to deliver high doses of radiation therapy (equivalent to SBRT doses) in one fraction. These treatments would be delivered sequentially, therefore, the total number of fractions. The only technique that would not be approvable would be SBRT because SBRT cannot be combined with any other form of radiation therapy • Deleted Additional Resources • Removed “physician review” language
January 2022	<p>Add the following under Proton Beam Radiation Therapy:</p> <ul style="list-style-type: none"> • 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



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*National Imaging Associates, Inc.	
Clinical guidelines: HODGKIN LYMPHOMA	Original Date: June 2013
Radiation Oncology	Last Revised Date: May 2023
Guideline Number: NIA_CG_132	Implementation Date: January 2024

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.*
- *Where a specific clinical indication is not directly addressed in this guideline, medical necessity determination will be made based on widely accepted standard of care criteria. These criteria are supported by evidence-based or peer-reviewed sources such as medical literature, societal guidelines and state/national recommendations.*

INDICATIONS FOR RADIATION THERAPY AND TREATMENT OPTIONS

2D and 3D conformal radiation therapy techniques are considered medically necessary for treatment of Hodgkin Lymphoma.¹⁻⁴

- **Combined Modality Therapy (CMT):**
 - Stage I-II (non-bulky disease): 20-30 Gy up to 20 fractions
 - Stage IB-IIB (non-bulky disease): 30 Gy up to 20 fractions
 - Stage I-IV (bulky disease): 30-36 Gy up to 24 fractions
 - Sites of Deauville 4-5 and PR to chemotherapy: 36-45 Gy up to 30 fractions
- **ISRT Alone (uncommon, except for LPHL)**
 - Involved regions: 30-36 Gy up to 24 fractions
 - Uninvolved regions: 25-30 Gy up to 20 fractions
- **Palliative:** 4-30 Gy up to 10 fractions for symptom control

TREATMENT OPTIONS TO BE REVIEWED ON A CASE-BY-CASE BASIS

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 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 < 13.5 Gy, V20 < 30%, and V5 < 55%.

Stereotactic Body Radiation Therapy⁵

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.

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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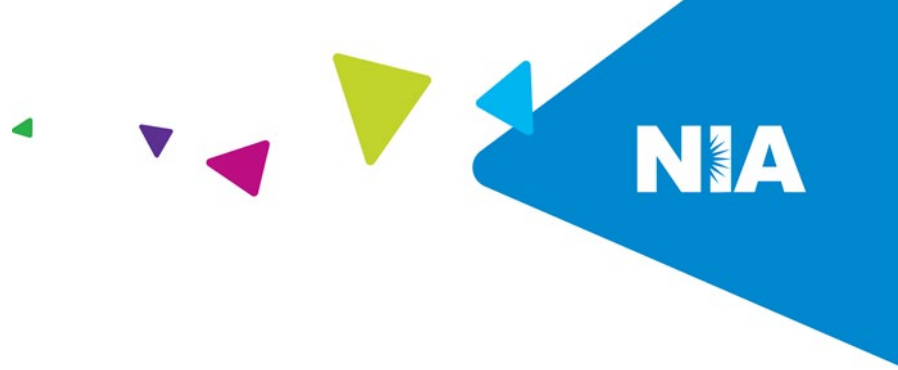
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POLICY HISTORY

Date	Summary
May 2023	<p>Clarified/updated radiation dose:</p> <ul style="list-style-type: none">● Combined Modality Therapy (CMT):<ul style="list-style-type: none">○ Stage I-II (non-bulky disease): 20-30Gy up to 20 fractions○ Stage IB-IIB (non-bulky disease): 30Gy up to 20 fractions○ Stage I-IV (bulky disease): 30-36Gy up to 24 fractions○ Sites of Deauville 4-5 and PR to chemotherapy: 36-45Gy up to 30 fractions● ISRT Alone (uncommon, except for LPHL)<ul style="list-style-type: none">○ Involved regions: 30-36Gy up to 24 fractions○ Uninvolved regions: 25-30Gy up to 20 fractions● Palliative: 4-30Gy up to 10 fractions for symptom control● Deleted Additional Resources● Replaced “Treatment Options Requiring Physician Review” with “Treatment Options to be reviewed on a case-by-case basis”
February 2022	Added NCCN panel recommends limiting Mean Lung Dose to < 13.5Gy, V20 <30%, and V5 <55%.

Reviewed / Approved by NIA Clinical Guideline Committee

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*National Imaging Associates, Inc.	
Clinical guideline: HYPERTHERMIA	Original Date: November 2013
CPT Codes: 77600, 77605, 77610, 77615, 77620	Last Revised Date: May 2023
Guideline Number: NIA_CG_227	Implementation Date: January 2024

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.*
- *Where a specific clinical indication is not directly addressed in this guideline, medical necessity determination will be made based on widely accepted standard of care criteria. These criteria are supported by evidence-based or peer-reviewed sources such as medical literature, societal guidelines and state/national recommendations.*

INDICATIONS FOR HYPERTHERMIA WITH RADIATION THERAPY

- Superficially recurrent melanoma¹
- Chest wall recurrence of breast cancer²⁻¹²
- 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 cannot 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 approval¹³ for the “palliative management of certain solid surface and subsurface malignant tumors (i.e. melanoma, squamous or basal cell tumors, adenocarcinoma, or sarcoma) that are progressive or recurrent despite conventional radiation therapy.”¹⁴ 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 Institute¹⁵)

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**^{16,17} - 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**¹⁸ - 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.

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POLICY HISTORY

Date	Summary
May 2023	Deleted additional resources
January 2022	No significant changes



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*National Imaging Associates, Inc.	
Clinical guidelines: INTENSITY-MODULATED RADIATION THERAPY (IMRT) FOR OTHER CANCERS	Original Date: June 2013
CPT codes: 77385, 77386, G6015, G6016	Last Revised Date: May 2023
Guideline Number: NIA_CG_223	Implementation Date: January 2024

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.*
- *Where a specific clinical indication is not directly addressed in this guideline, medical necessity determination will be made based on widely accepted standard of care criteria. These criteria are supported by evidence-based or peer-reviewed sources such as medical literature, societal guidelines and state/national recommendations.*

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.

- | | |
|---|--|
| <ul style="list-style-type: none"> • Anal Cancer • Bone Metastases • Breast Cancer • Cervical Cancer • CNS Cancer • Colon Cancer • Rectal Cancer • Endometrial Cancer | <ul style="list-style-type: none"> • 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 |
|---|--|

- Bladder Cancer
- Multiple Myeloma
- Vulvar Cancer
- Esophageal cancer
- Pleural Mesothelioma
- Soft Tissue Sarcoma
- Thyroid cancer

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)
- Prostate cancer
- Trachea cancer
- Thyroid cancer (except for palliative radiation)
- 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
- Pediatric patients less than 21 years with a radiosensitive tumor
- Adjuvant radiation therapy for pancreatic cancer after Whipple Surgery
- Extremity sarcomas located within the proximal lower extremity (i.e., thigh, groin)
- Thymomas and Thymic Carcinomas

ADDITIONAL CONDITIONS (To be reviewed on a case-by-case basis)

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 (except for adjuvant radiation therapy for pancreatic cancer after Whipple Surgery)
- Pelvic bone cancer

- Primary or secondary liver cancer
- Rectal cancer (other than low-lying cancers treated like anal 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.

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
- When para-aortic nodes are being treated

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 60-70 Gy, respecting normal tissue sensitivity. For gross nodal disease, consider boost to 60-65 Gy while respecting normal tissue constraints.³⁻⁵
- When para-aortic nodes are being treated

Hippocampal Sparing Intensity Modulated Radiation Therapy for PCI⁶⁻⁸

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
 - 25 Gy 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
 - do not have leptomeningeal disease
 - Whose primary histology is not germ cell, small cell, lymphoma or unknown
- Dosage Guidelines
 - Standard doses vary between 20 Gy and 37.5 Gy in 5-15 fractions. Hippocampal avoidance with WBRT (HA-WBRT) (plus memantine) 30 Gy in 10 fractions is preferred for patients with a better prognosis. For patients with poor predicated prognosis and with symptomatic brain metastases, standard WBRT of 20 Gy in 5 fractions is a reasonable option.

Stage IIIB Non-Small Cell Lung Carcinoma (any N3, or T3/4N2)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)^{13, 14}

IMRT can be approved on a case-by-case basis for accelerated partial breast irradiation using 30 Gy in 5 fractions once a day regimen. Comparative 3D-CRT vs. IMRT plans is not required.

Pleural Mesothelioma¹⁵⁻²⁰

A randomized phase III trial in patients with non-metastatic pleural mesothelioma who underwent non-radical lung-sparing surgery found substantially greater overall survival with radical hemithoracic intensity-modulated RT (IMRT) compared to palliative RT.

Special attention should be paid to minimize radiation to the contralateral lung, as the risk of fatal pneumonitis with IMRT is excessively high when strict limits are not applied. The contralateral uninvolved mean lung dose should be kept as low as possible, preferably < 8.5 Gy. The low-dose volume should be minimized.

Postoperative RT for patients who have P/D, other recommended specific lung preserving techniques, should limit the ipsilateral lung dose to decrease risk of pneumonitis and keep total mean lung dose (MLD) < 21 Gy and V20 < 40% and contralateral lung V20 < 7% and MLD < 8 Gy.

Thymomas and Thymic Carcinomas²¹⁻²³

The NCCN Guideline states for thymomas and thymic carcinomas, IMRT is preferred over 3D-CRT.

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 consider 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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POLICY HISTORY

Date	Summary
May 2023	<ul style="list-style-type: none"> • Added new policies (Bladder Cancer, Multiple Myeloma, Vulvar Cancer, Esophageal cancer, Pleural Mesothelioma) • Removed from MEDICALLY NECESSARY INDICATIONS FOR INTENSITY-MODULATED RADIATION THERAPY (IMRT): esophageal, vulvar, and bladder cancer • Added: <ul style="list-style-type: none"> ○ Adjuvant radiation therapy for pancreatic cancer after Whipple Surgery ○ Cervical Cancer: When para-aortic nodes are being treated ○ Endometrial Cancer: When para-aortic nodes are being treated ○ Extremity sarcomas located within the proximal lower extremity (i.e., thigh, groin) ○ Pleural Mesothelioma (non-metastatic who underwent non-radical lung-sparing surgery) ○ Thyroid cancer (except for palliative radiation) ○ Thymomas and Thymic Carcinomas • Deleted additional resources
January 2022	<ul style="list-style-type: none"> • Added “low-lying rectal cancer treated like anal cancer” • Added Bladder cancer (other than palliative cases) • Under the section for Conditions Requiring Additional Physician Review: <ul style="list-style-type: none"> ○ Added Postoperative IMRT for Endometrial Cancer ○ Added Postoperative IMRT for Cervical Cancer ○ Added Hippocampal Sparing Intensity Modulated Radiation Therapy for PCI ○ Added Hippocampal Sparing Whole Brain Intensity Modulated Radiation Therapy ○ Added Stage IIIB NSCLC ○ Added Accelerated Partial Breast Irradiation (APBI)



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*National Imaging Associates, Inc.	
Clinical guideline: INTRAOPERATIVE RADIATION THERAPY (IORT)	Original Date: November 2013
CPT Codes: 77424, 77425	Last Revised Date: May 2023
Guideline Number: NIA_CG_226	Implementation Date: January 2024

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.*
- *Where a specific clinical indication is not directly addressed in this guideline, medical necessity determination will be made based on widely accepted standard of care criteria. These criteria are supported by evidence-based or peer-reviewed sources such as medical literature, societal guidelines and state/national recommendations.*

INDICATIONS FOR IORT

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.

Breast Cancer: Refer to NIA’s clinical guideline on Breast Cancer.¹⁻⁵

- Single Fraction Electron-beam IORT is considered medically necessary in accordance with ASTRO guidelines¹ if the following criteria are met:
 - Individual is 50 years of age or older with invasive cancer (DCIS is excluded)
 - T Stage: Tis or T1
 - Clinically node negative
 - Negative surgical margins
- The use of electronic brachytherapy for IORT (such as Intrabeam, Xofig and Papillon systems) is considered experimental, investigational, and/or unproven.⁶

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.⁷

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.⁸

Pancreatic Cancer: Refer to NIA’s clinical guideline on Pancreatic Cancer. IORT for pancreatic cancer may be reasonable for patients undergoing resection that may result in a closer involved margin⁹. Cases will be reviewed on a case-by-case basis.

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.^{10,11}

Soft Tissue Sarcoma: IORT (with photons or electrons) is considered medically necessary as a boost treatment at time of surgery for cervical cancer, colorectal cancer, pancreatic cancer, and soft tissue sarcomas if either of the following criteria is met:¹²

- 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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POLICY HISTORY

Date	Summary
May 2023	<ul style="list-style-type: none">Deleted additional resourcesRemoved “requires physician review” from IORT for pancreatic cancer
January 2022	No changes

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*National Imaging Associates, Inc.	
Clinical guideline: METASTATIC DISEASE	Original Date: November 2013
CPT Codes: All Treatment Modalities	Last Revised Date: May 2023
Guideline Number: NIA_CG_228	Implementation Date: January 2024

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.*
- *Where a specific clinical indication is not directly addressed in this guideline, medical necessity determination will be made based on widely accepted standard of care criteria. These criteria are supported by evidence-based or peer-reviewed sources such as medical literature, societal guidelines and state/national recommendations.*

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 a clinical rationale for additional fractions and will be reviewed on a case-by-case basis.

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

- Treatment beyond ten fractions for 2D-3D-CRT requires a clinical rationale for additional fractions and will be reviewed on a case-by-case basis.
- **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 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 include^{2,3,4,5}
 - Unresectable metastatic liver tumors
 - Unresectable metastatic liver tumors from primary colorectal cancer
 - Unresectable primary hepatocellular carcinoma
 - Unresectable neuroendocrine tumors

†Note: Absolute Contraindication⁶

- Fulminant liver failure (absolute)

‡Note: Considerations/Relative Contraindications⁶

- 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 Disease⁷**
 - 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 presentation of clinical rationale and documentation for the proposed treatment modality and plan and will be reviewed on a case-by-case basis.

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POLICY HISTORY

Date	Summary
May 2023	<ul style="list-style-type: none">Deleted Additional ResourcesRemoved “physician review” language
January 2022	<ul style="list-style-type: none">Added indications for metastasis to lungUnder “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 contraindicationsWithin Oligometastatic Disease, increased the range of metastatic lesions from “One (1) to Four (4)” to “One (1) to Five (5)”

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*National Imaging Associates, Inc.	
Clinical Guideline: NEUTRON BEAM THERAPY (NBT)	Original Date: November 2013
CPT Codes: 77422, 77423	Last Revised Date: May 2023
Guideline Number: NIA_CG_229	Implementation Date: January 2024

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 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.

REFERENCES

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POLICY HISTORY

Date	Summary
May 2023	Deleted Additional Resources
January 2022	No changes

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*National Imaging Associates, Inc.	
Clinical Guideline: NON-HODGKIN'S LYMPHOMA	Original Date: June 2013
Radiation Oncology	Last Revised Date: May 2023
Guideline Number: NIA_CG_133	Implementation Date: January 2024

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.*
- *Where a specific clinical indication is not directly addressed in this guideline, medical necessity determination will be made based on widely accepted standard of care criteria. These criteria are supported by evidence-based or peer-reviewed sources such as medical literature, societal guidelines and state/national recommendations.*

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:

- Definitive Radiation:
 - Follicular lymphoma (24-30 Gy, or 36 Gy if bulky) up to 24 fractions¹⁻³
 - Mantle cell lymphoma (24-36 Gy) up to 24 fractions¹⁻³
 - MALT lymphoma – Marginal Zone (24-30 Gy) up to 20 fractions¹⁻³
 - Gastric: 24-30 Gy up to 20 fractions
 - Orbital and Salivary Gland: 4Gy in 2 fractions for selected patients (e.g., elderly, patients with Sjogren syndrome, otherwise 24 Gy up to 16 fractions
 - Diffuse large B cell lymphoma (30-55 Gy) up to 37 fractions^{1,3}
 - Consolidation after chemotherapy:
 - CR (Deauville 1-3): 30-36 Gy up to 20 fractions
 - PR (Deauville 4): 36-50 Gy up to 28 fractions
 - Refractory Disease (Deauville 4-5): 40-55 Gy up to 31 fractions
 - Primary treatment (without chemoimmunotherapy): 40-55 Gy up to 30 fractions

- In combination with hematopoietic cell transplantation: 20-36 Gy up to 24 fractions depending on sites of disease and prior RT exposure
- Prophylactic testicular irradiation: 25-30 Gy up to 20 fractions
- Primary cutaneous anaplastic large cell lymphoma⁴:
 - Consolidation after chemotherapy CR: 30-36 Gy up to 24 fractions
 - Complementary after PR: 30-50 Gy up to 28 fractions
 - Primary treatment for refractory or non-candidates for chemotherapy: 40-55 Gy up to 31 fractions
 - In combination with hematopoietic cell transplantation: 20-36 Gy up to 24 fractions depending on sites of disease and prior RT exposure
 - Hypofractionation for older patients and unfavorable prognosis: 12 Gy in 6 fractions, 8 Gy in 2 fractions both cautiously depending on the volume of the disease
- NK/T Lymphoma⁴
 - Primary treatment: 50-55 Gy up to 31 fractions
 - Combined modality: 45-56 Gy up to 32 fractions
 - Combined modality (non-asparaginase-based):
 - Sequential 45-50.4 Gy up to 28 fractions
 - Sandwich: 56 Gy up to 32 fractions
 - Concurrent
 - 50 Gy up to 28 fractions in combination with DeVIC
 - 50-54 Gy up to 30 fractions in combination with Cisplatin followed by VIPD
- Localized chronic lymphocytic leukemia (CLL) and Small Lymphocytic Lymphoma (SLL): 24-30 Gy up to 17 fractions⁵
- Palliative dose (up to 10 fractions) for symptom control
 - FL/MZL/MCL/SLL: 4 Gy in 1-2 fractions maybe repeated as needed, doses up to 30 Gy in 10 fractions may be appropriate in select circumstances (e.g., tumors \geq 6cm, SUV \geq 10)
 - DLBCL/HGBL/PMBL/Gray zone lymphoma with Burkitt lymphoma: 20-30 Gy up to 10 fractions
 - NK/T lymphoma: 20-36 Gy up to 18 fractions
 - AIDS-related B-cell lymphomas and PTLN: based on underlying histologic subtype and treatment intent

Unless otherwise indicated, standard radiation fractionation consists of 1.5 Gy to 2.0 Gy per day. ¹⁻³

Total Skin Electron Beam Therapy (TSEBT)

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

- Dosage Guidelines:

- 8-36 Gy, 1- 2 Gy 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 4-12 Gy

TREATMENT OPTIONS (WILL BE REVIEWED ON A CASE-BY-CASE BASIS)

Intensity modulated radiation therapy (IMRT)⁶

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 Therapy⁷

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.⁷ 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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POLICY HISTORY

Date	Summary
May 2023	<p>Clarified/updated radiation doses:</p> <ul style="list-style-type: none"> • Definitive Radiation: <ul style="list-style-type: none"> ○ Follicular lymphoma (24-30Gy, or 36Gy if bulky) up to 24 fractions¹ <ul style="list-style-type: none"> ▪ Mantle cell lymphoma (24-36Gy) up to 24 fractions¹ ▪ MALT lymphoma – Marginal Zone (24-30Gy) up to 20 fractions¹ <ul style="list-style-type: none"> • Gastric: 24-30Gy up to 20 fractions • Orbital and Salivary Gland: 4Gy in 2 fractions for selected patients (e.g., elderly, patients with Sjogren syndrome, otherwise 24Gy up to 16 fractions) ▪ Diffuse large B cell lymphoma (30-55Gy) up to 37 fractions¹ <ul style="list-style-type: none"> • Consolidation after chemotherapy: <ul style="list-style-type: none"> ○ CR (Deauville 1-3): 30-36Gy up to 20 fractions ○ PR (Deauville 4): 36-50Gy up to 28 fractions ○ Refractory Disease (Deauville 4-5): 40-55Gy up to 31 fractions • Primary treatment (without chemoimmunotherapy): 40-55Gy up to 30 fractions • In combination with hematopoietic cell transplantation: 20-36Gy up to 24 fractions depending on sites of disease and prior RT exposure • Prophylactic testicular irradiation: 25-30Gy up to 20 fractions ▪ Primary cutaneous anaplastic large cell lymphoma : <ul style="list-style-type: none"> • Consolidation after chemotherapy CR: 30-36Gy up to 24 fractions • Complementary after PR: 30-50Gy up to 28 fractions • Primary treatment for refractory or non-candidates for chemotherapy: 40-55Gy up to 31 fractions • In combination with hematopoietic cell transplantation: 20-36Gy up to 24 fractions depending on sites of disease and prior RT exposure • Hypofractionation for older patients and unfavorable prognosis: 12Gy in 6 fractions, 8Gy in 2 fractions both cautiously depending on the volume of the disease ▪ NK/T Lymphoma <ul style="list-style-type: none"> • primary treatment: 50-55Gy up to 31 fractions • combined modality: 45-56Gy up to 32 fractions • combined modality (non-asparaginase-based): <ul style="list-style-type: none"> ○ Sequential 45-50.4Gy up to 28 fractions ○ Sandwich: 56Gy up to 32 fractions



	<ul style="list-style-type: none"> ○ Concurrent <ul style="list-style-type: none"> ▪ 50Gy up to 28 fractions in combination with DeVIC ▪ 50-54Gy up to 30 fractions in combination with Cisplatin followed by VIPD ▪ 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 <ul style="list-style-type: none"> ○ FL/MZL/MCL/SLL: 4Gy in 1-2 fractions maybe repeated as needed, doses up to 30Gy in 10 fractions may be appropriate in select circumstances (e.g., tumors \geq 6cm, SUV \geq 10) ○ DLBCL/HGBL/PMBL/Gray zone lymphoma with Burkitt lymphoma: 20-30Gy up to 10 fractions ○ NK/T lymphoma: 20-36Gy up to 18 fractions ○ AIDS-related B-cell lymphomas and PTLD: based on underlying histologic subtype and treatment intent ● Deleted Additional Resources ● Changed “Treatment options requiring physician review” to Treatment Options (will be reviewed on a case-by-case basis)
January 2022	Added Total Skin Electron Beam Therapy (TSEBT) along with dosage guidelines



Reviewed / Approved by NIA Clinical Guideline Committee

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*National Imaging Associates, Inc.	
Clinical Guideline: NON-SMALL CELL LUNG CANCER	Original Date: March 2011
Radiation Oncology	Last Revised Date: May 2023
Guideline Number: NIA_CG_122	Implementation Date: January 2024

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.*
- *Where a specific clinical indication is not directly addressed in this guideline, medical necessity determination will be made based on widely accepted standard of care criteria. These criteria are supported by evidence-based or peer-reviewed sources such as medical literature, societal guidelines and state/national recommendations.*

INDICATIONS FOR RADIATION THERAPY

Three-dimensional conformal radiation therapy (3D-CRT) is considered medically necessary for the following clinical indications¹:

- **Post-Operative Radiation Therapy¹:**
 - Clinical stage I/II upstaged surgically to N2+
 - Positive Nodes (N 2-3); **or**
 - Positive or close margins

Dosage Guidelines¹:

- Extracapsular nodal extension or positive margins: 54-60 Gy up to 33 fractions
- Gross Residual Tumor 60-70 Gy up to 39 fractions
- Negative margins: 50-54 Gy up to 30 fractions

- **Pre-Operative Radiation Therapy¹:**
 - T3-4, N0-N1; **or**
 - Resectable Superior Sulcus Tumors; **or**
 - N2 disease (Stage IIIA, T 1-3, N2)

Dosage Guidelines¹:

- 45-54 Gy up to 30 fractions

- Inoperable – Definitive¹:
 - Stage I disease (T1-2a, N0, M0)
 - Stage II and Stage III disease (T2b-T4, N0, M0 or T1-4, N1-3, M0)

OR

- Surgery Refused

Dosage Guidelines¹:

- 60-70 Gy up to 39 fractions

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

- Palliative Radiation Therapy is considered medically necessary for Stage IV (M1) disease to relieve pain, airway or endobronchial obstruction, and other symptoms¹
 - Shorter courses of RT are preferred for patients with poor performance status and/or shorter life expectancy because they provide similar pain relief as longer courses, although there is a higher potential need for retreatment²⁻⁵
 - For palliation of thoracic symptoms, higher dose/longer-course thoracic RT (e.g., ≥30 Gy in 10 fractions) is associated with modestly improved survival and symptoms, particularly in patients with good performance status^{6,7}
 - Single-fraction stereotactic RT of 12–16 Gy produced better control of pain response and local control of non-spine bone metastases compared to standard 30 Gy in 10 fractions in a randomized phase II trial and may be promising for patients with longer expected survival⁸

Dosage Guidelines:

- 30-45 Gy up to 15 fractions

For hypofractionated palliative radiation, standard radiation fractionation consists of 2.5-3 Gy.

TREATMENT OPTIONS (Will be reviewed on a case-by-case basis)

Endobronchial Brachytherapy is considered medically necessary for the following clinical indications¹:

- 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.

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.

IMRT – Stage IIIB (any N3, or T3/4N2)⁹ , and No-Fly Zone Lesions and/or T3N0 for ablative therapy:

- IMRT is approvable for definitive treatment of stage IIIB/IIIC (any N3, or T3/4N2) NSCLC. A comparative plan is not required.
- IMRT is approvable for No-Fly Zone Lesions for ablative therapy (Up to 15 fractions)

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 be reviewed on a case-by-case basis 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.¹⁰

Stereotactic Body Radiation Therapy (SBRT) is considered medically necessary for patients with inoperable (including high-risk patients able to tolerate sublobar resection but not lobectomy) Stage I or II disease (including node-negative stage IIB) or patients who refuse to have surgery or for a previously irradiated field¹

Dosage Guidelines:

- Delivered at 5 fractions or less

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.

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POLICY HISTORY

Date	Summary
May 2023	<p>Added:</p> <p>Post-Operative Radiation Therapy:</p> <ul style="list-style-type: none"> • Clinical stage I/II upstaged surgically to N2+ • Positive Nodes (N 2-3) <p>(Under Palliative Radiation Therapy)</p> <ul style="list-style-type: none"> • Shorter courses of RT are preferred for patients with poor performance status and/or shorter life expectancy because they provide similar pain relief as longer courses, although there is a higher potential need for retreatment • For palliation of thoracic symptoms, higher dose/longer-course thoracic RT (e.g., ≥30Gy in 10 fractions) is associated with modestly improved survival and symptoms, particularly in patients with good performance status • Single-fraction stereotactic RT of 12–16Gy produced better control of pain response and local control of non-spine bone metastases compared to standard 30Gy in 10 fractions in a randomized phase II trial and may be promising for patients with longer expected survival • Dosage Guidelines: <ul style="list-style-type: none"> 30-45Gy up to 15 fractions <p>Added language in parentheses:</p> <ul style="list-style-type: none"> • Stereotactic Body Radiation Therapy (SBRT) is considered medically necessary for patients with inoperable (including high-risk patients able to tolerate sublobar resection but not lobectomy) Stage I or II disease (including node-negative stage IIB) or patients who refuse to have surgery or for a previously irradiated field • Added No-Fly Zone Lesions under IMRT : <p>IMRT – Stage IIB (any N3, or T3/4N2) , and No-Fly Zone Lesions and/or T3N0 for ablative therapy:</p> <ul style="list-style-type: none"> ○ IMRT is approvable for definitive treatment of stage IIB/IIIC (any N3, or T3/4N2) NSCLC. A comparative plan is not required. ○ IMRT is approvable for No-Fly Zone Lesions for ablative therapy (Up to 15 fractions) • Deleted Additional Resources • Removed “physician review” language
January 2022	<ul style="list-style-type: none"> • Within Palliative Radiation Therapy, added “For hypofractionated palliative radiation, standard radiation fractionation consists of 2.5-3Gy.” • Added IMRT – Stage IIB (any N3, or T3/4N2)



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*National Imaging Associates, Inc.	
Clinical guidelines: NON-CANCEROUS CONDITIONS	Original Date: March 2015
Radiation Oncology	Last Revised Date: May 2023
Guideline Number: NIA_CG_135	Implementation Date: January 2024

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.*
- *Where a specific clinical indication is not directly addressed in this guideline, medical necessity determination will be made based on widely accepted standard of care criteria. These criteria are supported by evidence-based or peer-reviewed sources such as medical literature, societal guidelines and state/national recommendations.*

INDICATIONS FOR RADIATION THERAPY

2D or 3D Conformal (3D CRT) is considered medically necessary for several non-malignant conditions, including but not limited to:¹⁻¹²

- Prevention of keloid scars as an adjunctive therapy following excisional surgery: superficial x-ray, electron beam, or conventional isodose technique photon beam therapy in 4 or fewer fractions¹³
- Heterotopic ossification: 7 Gy to 8 Gy in a single fraction of 2D
- Pterygium in cases that cannot be medically managed: contact beta brachytherapy in 3 fractions
- Villonodular synovitis (recurrent after resection, or diffuse or bulky disease-causing bone destruction: 28 or fewer fractions of 2D/3D-CRT
- Pinealoma (pineal parenchymal tumors): Postoperative radiation for incomplete resection, 45-60 Gy in 25-30 fractions of 3D-CRT, and from 12-36 Gy of SRS/FSRT
- Pituitary adenoma for medically inoperable cases, recurrence after surgery, incomplete resection, or persistence of elevated hormones after resection of functional adenomas: 3D-CRT, SRS, or IMRT, 45-54 Gy up to 30 fractions
- Precancerous melanosis (lentigo maligna, Hutchinson's melanotic freckle, or circumscribed precancerous melanosis of Dubreuilh): for recurrence or more extensive lesions, superficial and orthovoltage therapy, 35–57 Gy in 5–23 fractions

- Rosai-Dorfman disease for lesions involving the airway not responding to more conservative measures, up to 22 fractions of 2D/3D
- Splenomegaly (hypersplenism): Very low doses of radiation on a less than daily basis, 10 or fewer fractions of 2D/3D
- Total body irradiation (TBI): For non-malignant, pre-malignant and quasi-benign marrow disorders such as aplastic anemia or myelodysplastic disorders^{14,15}
 - 12-15 Gy given in 6 to 12 fractions over 3-5 days, fractionated in 2 to 3 treatments per day
 - Low-dose TBI, with doses of 2-6 Gy given in 1 to 4 fractions in combination with chemotherapy, is an effective conditioning regimen for hematopoietic stem cell transplantation in patients who cannot tolerate myeloablation due to age or comorbidities
- Peyronie's disease (Morbus Peronie, Induratio penis plastica): 2D, orthovoltage, or electron beam radiation in 5 or fewer fractions
- Parotid adenoma: for > 4 cm, positive margin status, and multinodularity, up to 30 fractions
- Paraganglioma (chromaffin positive): for unresectable, recurrence, or as adjuvant therapy for incomplete resection, 25-28 fractions of 3D/IMRT, SRS 12-18 Gy
- Orbital pseudotumor (lymphoid hyperplasia): Up to 10 fractions of 2D/3D
- Orbital myositis (failed conservative therapy): up to 15 fractions of 2D/3D
- Non-cutaneous neurofibromas: for symptomatic unresectable non-cutaneous lesions, up to 30 fractions
- Lethal midline granuloma: for localized presentations or in conjunction with systemic therapy, 45-50 Gy up to 25 fractions
- Lymphangiomas (capillary, cavernous, cystic hygromas, and lymphangial): for refractory lesions with repeated recurrence after resection (, and chylothorax due to pleural involvement, 20-40 Gy in 10-20 fractions
- Langerhans cell histiocytosis (LCH): for localized growth, up to 28 fractions of 3D
- Inverted papilloma: for incomplete resection, or suspected malignant component, 45-70.4 Gy up to 39 fractions
- Hyperthyroidism/thyroiditis: systemic 131-I
- Hemangiomas (brain, spinal cord, subglottis, glottis, liver, GI tract, urinary tract, joints and orbit): Up to 30 fractions of IMRT
- Gynecomastia: up to 5 fractions of electron beam therapy
- Graves' ophthalmopathy: up 20 10 fractions of 2D/3D
- Gorham-Stout syndrome (disappearing bone syndrome): up to 25 fractions of 3D
- Giant cell tumor of bone (osteoclastoma): for unresectable, up to 30 fractions
- Dupuytren's contracture (fibromatosis) of hands/feet: up to 10 fractions of 2D or electron beam
- Aneurysmal bone cyst: as the last resort, up to 10 fractions
- Angiofibroma of nasopharynx (juvenile nasopharyngeal angiofibroma): for unresectable disease, up to 20 fractions
- Angiomatosis retinae (von Hippel Lindau syndrome): beta plaque

- Bowen's disease (squamous cell carcinoma in situ)/Erythroplasia of Queyrat: when typical alternatives (surgery, electrodesiccation and curettage, topical 5FU), are not possible, superficial radiation up to 20 fractions
- Desmoid tumor: for inoperable cases, up to 28 fractions of 3D
- Degenerative skeletal disorder: for symptomatic degenerative skeletal and joint disorders (i.e., plantar fasciitis, trochanteric bursitis) refractory to conventional treatments, up to 8 fractions of 2D
- Choroidal hemangioma: for diffuse lesions, especially if near the macula or papilla, and for those not responding to other treatments, LDR brachytherapy, or 2D/3D up to 20 fractions
- Castleman's disease (giant lymph node hyperplasia): for orbital pseudotumor and Waldeyer's ring, LDR brachytherapy, or 2D/3D up to 25 fractions
- Carcinoid tumors: for symptomatic unresectable non-secretory, or secreting tumors, up to 25 fractions
- Hypersalivation of amyotrophic lateral sclerosis (ALS): when other means of management are ineffective or impractical, up to 4 fractions

Stereotactic Radiation Therapy (SRS, SBRT) is considered medically necessary when used in the treatment of non-malignant cranial lesions including the following:^{16,17}

- 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 for other non-malignant conditions utilizing proton beam, stereotactic radiation therapy (SBRT), or intensity modulated radiation therapy (IMRT) modalities will be reviewed on a case-by-case basis.

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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POLICY HISTORY

Date	Summary
May 2023	<ul style="list-style-type: none">• Updated/expanded INDICATIONS FOR RADIATION THERAPY• Added criteria for SRS/SBRT therapy• Removed Additional Resources
January 2022	No significant changes



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*National Imaging Associates, Inc.	
Clinical guidelines PANCREATIC CANCER	Original Date: June 2013
Radiation Oncology	Last Revised Date: May 2023
Guideline Number: NIA_CG_134	Implementation Date: January 2024

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.*
- *Where a specific clinical indication is not directly addressed in this guideline, medical necessity determination will be made based on widely accepted standard of care criteria. These criteria are supported by evidence-based or peer-reviewed sources such as medical literature, societal guidelines and state/national recommendations.*

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 metastatic¹

- No standard treatment regimen currently exists for this subset of patients. If neoadjuvant radiation therapy is delivered, a dose of 45-54 Gy in 1.8-2.5 Gy fractions or 36 Gy in 2.4 fractions are viable options.

Adjuvant (Post-Operative) Resectable Without Evidence of Metastatic Disease¹

- For resected cases (45-50.4 Gy in 1.8-2 Gy fractions) with potential boost to the high-risk regions (5-9 Gy). Up to 33 fractions. IMRT should be considered for post-operative radiation after a pancreatoduodenectomy (Whipple procedure).

Unresectable/Locally Advanced Without Evidence of Metastatic Disease¹

- Radiation delivered in 45-54 Gy (1.8-2.5 Gy fractions). Up to 30 fractions. More protracted courses delivering high doses through a hypofractionated approach (67.5 Gy in 15 fractions or 75Gy in 25 fractions) are also acceptable.

Palliative¹

- Radiation delivered in 25-36 Gy in 2.4-5.0 Gy 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

- RT dose generally consists of 45-54 Gy in 1.8 to 2.0 Gy fractions. Up to 30 fractions.¹

TREATMENT OPTIONS (Will be reviewed on a case-by-case basis)

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 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 ≥ 18 Gy. If only one kidney is functional, not more than 10% of the volume can receive ≥ 18 Gy. Maximum dose to stomach, duodenum, and jejunum is 55 Gy. Mean dose of liver cannot exceed 30 Gy. Maximum dose to D0.03cc of spinal cord must be ≤ 45 Gy.

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

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. IMRT to 60 Gy in 15 fractions is an alternative to SBRT for ablative treatment.

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 patient's 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 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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POLICY HISTORY

Date	Summary
May 2023	<ul style="list-style-type: none"> • Added to SBRT: IMRT to 60 Gy in 15 fractions is an alternative to SBRT for ablative treatment. • Added to Unresectable, locally advanced: More protracted courses delivering high doses through a hypofractionated approach (67.5 Gy in 15 fractions or 75 Gy in 25 fractions) are also acceptable. • Added to post-operative radiation: IMRT should be considered for post-operative radiation after a pancreateoduodenectomy (Whipple procedure). • Added to Adjuvant (post-operative radiation): Up to 33 fractions • Added Local Recurrence after Resection without Evidence of Systemic Metastatic Disease: RT dose generally consists of 45-54 Gy in 1.8 to 2.0 Gy fractions. Up to 30 fractions • Deleted Additional Resources • Changed “Treatment options requiring physician review” to Treatment Options (will be reviewed on a case-by-case basis)
January 2022	Added: Dose constraints for neoadjuvant, definitive, palliative and recurrent disease based on RTOG 1102 and dose constraints for adjuvant therapy based on RTOG 0848.



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*National Imaging Associates, Inc.	
Clinical guideline PROSTATE CANCER	Original Date: March 2011
Radiation Oncology	Last Revised Date: May 2023
Guideline Number: NIA_CG_124	Implementation Date: January 2024

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.*
- *Where a specific clinical indication is not directly addressed in this guideline, medical necessity determination will be made based on widely accepted standard of care criteria. These criteria are supported by evidence-based or peer-reviewed sources such as medical literature, societal guidelines and state/national recommendations.*

MEDICALLY NECESSARY INDICATIONS FOR RADIATION THERAPY^{1,2}

EBRT/IMRT hypofractionation of 20-28 fractions are recommended to treat localized prostate cancer when pelvic nodes are not treated. Other treatment regimens require clinical documentation that supports medical necessity and will be reviewed on a case-by-case basis.

Very Low Recurrence Risk: (Primary Tumor Stage [T] is T1c, PSA <10 ng/ml, and Grade Group 1, PSA density <0.15ng/nl per g, < 3 biopsy cores positive with ≤ 50% cancer in each)

- Active surveillance (patients are encouraged to pursue active surveillance)
- External Beam Radiation
 - Clinicians should not electively radiate pelvic lymph nodes³⁻⁵
 - 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 alone

Low Recurrence Risk: (Primary Tumor Stage [T] is T1-T2a, PSA <10 ng/ml, and Grade Group 1

- Active surveillance (patients are encouraged to pursue active surveillance)

- External Beam Radiation Therapy
 - Clinicians should not electively radiate pelvic lymph nodes³⁻⁵
 - Highly conformal radiation therapy technique (3D-CRT/IMRT with IGRT). Hypofractionation 20-28 fractions (with or without radiation to the seminal vesicles, regardless of patient age, comorbidity, anatomy, or urinary function²
 - 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 alone

Favorable Intermediate Recurrence Risk: Grade Group 1 with PSA 10-<20 ng/mL or clinical stage T2b-c and < 50%* biopsy cores positive OR Grade Group 2 with PSA <10 ng/mL and clinical stage T1-2a and < 50% biopsy cores positive

- Active surveillance (discussed with patient as treatment option)
- External Beam Radiation Therapy
 - Clinicians should not electively radiate pelvic lymph nodes³⁻⁵
 - Highly conformal radiation therapy technique (3D-CRT/IMRT with IGRT). Hypofractionation- 20-28 fractions (with or without radiation to the seminal vesicles, regardless of patient age, comorbidity, anatomy, or urinary function²
 - 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 alone

Unfavorable Intermediate Recurrence Risk: Grade Group 1 with PSA 10-<20 ng/mL and clinical stage T2b-c OR Grade Group 2 with PSA 10-<20 ng/mL and/or clinical stage T2b-c and/or ≥ 50%* biopsy cores positive OR Grade Group 3 with PSA < 20 ng/mL

- External Beam Radiation Therapy
 - Prophylactic nodal radiation can be considered if additional risk assessments suggest aggressive tumor behavior¹
 - Highly conformal radiation therapy technique (3D-CRT/IMRT with IGRT). Hypofractionation- 20-28 fractions (with or without radiation to the seminal vesicles, regardless of patient age, comorbidity, anatomy, or urinary function²
 - When treating the pelvic lymph nodes with radiation, clinicians should utilize intensity-modulated radiation therapy (IMRT) with doses between 45-52 Gy³⁻⁵
 - 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 15-28 fractions

High Recurrence Risk: (Primary Tumor Stage [T] T3a OR PSA > 20 ng/ml OR Grade Group 4 or Grade Group 5

- External Beam Radiation Therapy
 - In patients with high-risk prostate cancer electing radiation therapy, clinicians may offer radiation to the pelvic lymph nodes³⁻⁵
 - When treating the pelvic lymph nodes with radiation, clinicians should utilize intensity-modulated radiation therapy (IMRT) with doses between 45-52 Gy³⁻⁵
 - Highly conformal radiation therapy technique (3D-CRT/IMRT with IGRT). Hypofractionation- 20-28 fractions (with or without radiation to the seminal vesicles, regardless of patient age, comorbidity, anatomy, or urinary function²
 - Up to 45 fractions are medically necessary when pelvic nodes are treated. Gross or PSMA-positive lymph nodes are boosted to 55.2 Gy in 23 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.
- Brachytherapy (LDR/HDR) boost combined with EBRT after 15-28 fractions.

Very High Recurrence Risk (Primary Tumor Stage [T] T3b-T4) OR Grade Group 4 or Grade Group 5 OR 2 or 3 high-risk features OR >4 cores with Grade Group 4 or 5

- External Beam Radiation Therapy
 - In patients with very high-risk prostate cancer electing radiation therapy, clinicians may offer radiation to the pelvic lymph nodes³⁻⁵
 - When treating the pelvic lymph nodes with radiation, clinicians should utilize intensity-modulated radiation therapy (IMRT) with doses between 45-52 Gy³⁻⁵
 - Highly conformal radiation therapy technique (3D-CRT/IMRT with IGRT). Hypofractionation- 20-28 fractions (with or without radiation to the seminal vesicles, regardless of patient age, comorbidity, anatomy, or urinary function²
 - Up to 45 fractions are medically necessary when pelvic nodes are treated. Gross or PSMA-positive lymph nodes are boosted to 55.2 Gy in 23 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.
- Brachytherapy (LDR/HDR) boost combined with EBRT in 15-28 fractions

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
 - Brachytherapy (LDR or HDR)
- One of the following must be met:

- Detectable PSA or initially undetectable PSA, but with recent detectable and rising values on 2 or more measurements with no evidence of metastatic disease
- Positive margins
- Seminal vesicle invasion or extracapsular extension.
- Gleason 8-10
- Pathological T3 disease

TREATMENT OPTIONS (Will be reviewed on a case-by-case basis)

The radiation treatment options below will be reviewed on a case-by-case 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. 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 review and clinical documentation that supports medical necessity.

DOSAGE GUIDELINES

- Conventional Fractionation up to 45 fractions
- Moderate Hypofractionation (preferred, for all but low-volume M1, including N1):
 - 3 Gy x 20 fractions
 - 2.7 Gy x 26 fractions
 - 2.5 Gy x 28 fractions
- Ultra-Hypofractionation (for all but N1 and M1):
 - 9.5 Gy x 4 fractions
 - 7.25-8 Gy x 5 fractions
 - 6.1 Gy x 7 fractions
- **Low-volume metastatic disease (either non-regional lymph node-only disease OR <4 bone metastases and without visceral/other metastasis)¹**
 - Per STAMPEDE phase 3 randomized trial,⁶ 55 Gy in 20 fractions (i.e., 2.75 Gy x 20) or 6 Gy x 6 fractions can be used.
 - Number and location of lesions is defined by conventional imaging¹
 - At this time, metastases defined only by PET imaging should not be used to exclude a patient from treatment of the primary tumor¹
- **High-volume metastatic disease (Visceral met, 4 or more bone mets with at least one metastasis beyond the pelvis vertebral column):**
 - Based on HORRAD⁷ & STAMPEDE trials no RT to prostate would be medically necessary.

- **Palliative Radiation Therapy (e.g., pain, obstruction)**
 - 8 Gy x 1
 - 20 Gy in 5 fractions
 - 30 Gy in 10 fractions
 - 37.5 Gy in 15 fractions
 - 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.^{1,2,8-12}
-

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 are 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.

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POLICY HISTORY

Date	Summary
May 2023	<ul style="list-style-type: none">• All the risk groups updated• Palliative Radiation Therapy moved down, with updated dosage guidelines• Deleted Additional Resources• Removed “physician review” language
January 2022	<ul style="list-style-type: none">• 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<ul style="list-style-type: none">○ 30Gy/10FX or○ 37.5Gy/15FX• Added Dosage Guidelines section within Treatment Options Requiring Physician Review

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*National Imaging Associates, Inc.	
Clinical guidelines: PROTON BEAM RADIATION THERAPY	Original Date: June 2013
CPT codes: 77520,77522,77523,77525	Last Revised Date: May 2023
Guideline Number: NIA_CG_221	Implementation Date: January 2024

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.*
- *Where a specific clinical indication is not directly addressed in this guideline, medical necessity determination will be made based on widely accepted standard of care criteria. These criteria are supported by evidence-based or peer-reviewed sources such as medical literature, societal guidelines and state/national recommendations.*

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.

MEDICALLY NECESSARY INDICATIONS FOR PROTON BEAM THERAPY (Will be reviewed on a case-by-case basis)

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 age¹

- 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 2 and 3 IDH-mutant diffuse glioma² and 1p19q codeleted tumors³) to reduce acute and late toxicity, especially for tumors located near critical OARs⁴
- 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)⁵
- Advanced (e.g., T4) and/or unresectable head and neck cancers⁶⁻¹⁷
- Cancers of the paranasal sinuses and other accessory sinuses

OTHER TREATMENT OPTIONS(Will be reviewed on a case-by-case basis)^{1, 4, 18}

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 2 and 3 IDH-mutant tumors [1] and 1p19q codeleted tumors))
- Soft tissue sarcoma (except for non-metastatic retroperitoneal sarcomas)
- 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 spread, 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.

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POLICY HISTORY

Date	Summary
May 2023	<ul style="list-style-type: none"> • Edited: Malignant and benign primary CNS tumors: Consider proton therapy for patients with good long-term prognosis (grade 2 and 3 IDH-mutant diffuse glioma² and 1p19q codeleted tumors³) to reduce acute and late toxicity, especially for tumors located near critical OARs. • Added reference: Radiation Therapy for IDH-Mutant Grade 2 and Grade 3 Diffuse Glioma: An ASTRO Clinical Practice Guideline, Halasz et al., Practical Radiation Oncology (2022) 12, 370-386 • Deleted Additional Resources • Removed “physician review” language
January 2022	<ul style="list-style-type: none"> • Under “Treatment at any age” <ul style="list-style-type: none"> ○ Added malignant and benign primary CNS tumors ○ 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” <ul style="list-style-type: none"> ○ 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)



Reviewed / Approved by NIA Clinical Guideline Committee:

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*National Imaging Associates, Inc.	
Clinical guidelines: SKIN CANCER	Original Date: May 2016
Radiation Oncology	Last Revised Date: May 2023
Guideline Number: NIA_CG_136	Implementation Date: January 2024

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.*
- *Where a specific clinical indication is not directly addressed in this guideline, medical necessity determination will be made based on widely accepted standard of care criteria. These criteria are supported by evidence-based or peer-reviewed sources such as medical literature, societal guidelines and state/national recommendations.*

INDICATIONS FOR RADIATION THERAPY

Basal & Squamous Cell Skin Cancer^{1, 2,3, 4}

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

- Definitive RT
 - Tumor diameter
 - 60-64 Gy over 6-7 weeks
 - 50-55 Gy over 3-4 weeks
 - 40 Gy over 2 weeks
 - 30 Gy in 5 fractions over 2-3 weeks
 - Tumor diameter ≥ 2 cm, T3/T4, or those with invasion of bone or deep tissue
 - 60-70 Gy over 6-7 weeks
 - 45-55 Gy over 3-4 weeks
- Post-operative RT/ Regional Disease

- Positive lymph nodes (not indicated for single, small (< 3cm) cervical lymph node harboring carcinoma, without extracapsular extension)
- Gross perineural spread
- Depth > 6mm
- Close or positive margins that cannot be corrected with further surgery
- Recurrence after a prior margin-negative resection
- T3 and T4 tumors
- Desmoplastic or infiltrative tumors in the setting of chronic immunosuppression
 - Lymph node regions, after lymph node dissection^{1, 2}
 - Negative margins, no ECE: 50-60 Gy over 5 to 6 weeks
 - Positive margins or ECE: 60-66 Gy over 6 to 7 weeks
 - Lymph node regions, without lymph node dissection
 - Clinically negative, at risk: 50 Gy over 5 weeks
 - Clinically positive: 60-70 Gy over 6 to 7 weeks
 - Clinically at-risk nerves: 50-60 Gy over 5 to 6 weeks

Melanoma⁵

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.

Dosage and Schedule Guidelines

- *Definitive Therapy:* may be considered as a treatment option for MIS, LM-type (i.e., high-CSD) in medically inoperable patients or those in whom surgical morbidity of complete resection would be prohibitive.
 - 64-70 Gy in 32–35 fractions over 6–7 weeks
 - 50-57.5 Gy in 20–23 fractions over 4–5 weeks
 - 35 Gy in 5 fractions over 1 week for fields < 3cm²
 - 32 Gy in 4 fractions once per week
- *Adjuvant Therapy/Regional Disease:* may be considered for select cases of high-risk desmoplastic melanoma based on a combination of risk factors for local recurrence. Risk factors for regional recurrence include gross and/or histologic extracapsular extension of melanoma in clinically (macroscopic) involved node(s), ≥ 1 parotid node, ≥ 2 cervical or axillary nodes, ≥ 3 inguinofemoral nodes, ≥ 3 cm cervical or axillary node, and/or ≥4 cm inguinofemoral node. Other risk factors include Breslow ≥4mm, head and neck primaries, ulceration, satellitosis, and perineural invasion.
 - 50-66 Gy in 25-33 fractions over 5-7 weeks
 - 48 Gy in 20 fractions over 4 weeks
 - 30 Gy in 5 fractions over 2 weeks (twice per week or every other day)
- *Palliative Therapy:*

- Unresectable nodal, satellite, or in-transit disease
- Residual local, satellite, or in-transit disease after prior treatment
- Symptomatic Extracranial Metastases
 - 24-27 Gy in 3 fractions over 1-1.5 weeks
 - 32 Gy in 4 fractions over 4 weeks
 - 40 Gy in 8 fractions over 4 weeks
 - 50 Gy in 20 fractions over 4 weeks
 - 30 Gy in 10 fractions over 2 weeks
 - 30 Gy in 5 fractions over 2 weeks
 - 20 Gy in 5 fractions over 1 week
 - 8 Gy in 1 fraction over 1 day

Merkel Cell Carcinoma⁶

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

Dosage and Schedule Guidelines

- *Definitive Therapy*: Unresectable, Surgery refused by patient, Surgery would result in significant morbidity
 - 60-66 Gy in 30–33 fractions over 6-7 weeks
- *Adjuvant RT*
 - Negative resection margins: 50-56 Gy
 - Microscopically positive resection margins: 56-60 Gy
 - Grossly positive resection margins and further resection not possible: 60-66 Gy
- *Regional Disease*
 - No SLNB or LN dissection
 - Clinically evident lymphadenopathy: 60-66 Gy
 - Clinically node negative, but at risk for subclinical disease: 46-50 Gy
 - SLNB without LN dissection
 - SLN negative — RT not routinely indicated: Observation
 - SLN positive: 50-56 Gy
 - After LN dissection with multiple involved nodes and/or extracapsular extension: 50-60 Gy

Cutaneous Lymphoma^{7, 8}

- *PTCL*
 - Consolidation after chemotherapy CR: 30-36 Gy
 - Complementary after PR: 40-50 Gy
 - RT as primary treatment for refractory or non-candidates for chemotherapy: 40-55 Gy

- In combination with HCT: 20-36 Gy, depending on sites of disease and prior RT exposure
- *Breast-implant associated ALCL*: 24-36 Gy for local residual disease
- *NK/T-cell lymphoma*
 - RT alone as primary treatment (if unfit for chemotherapy): 50-55 Gy
 - RT in combined modality therapy: 45-56 Gy
 - Combined modality therapy (non-asparaginase-based):
 - CCRT:
 - 50 Gy in combination with DeVIC (dexamethasone, etoposide, ifosfamide, and carboplatin)
 - 50-54 Gy in combination with cisplatin followed by VIPD (etoposide, ifosfamide, cisplatin, and dexamethasone)
 - Sequential chemoradiation: Modified SMILE regimen followed by RT 45-50.4 Gy for stage I-II disease
 - Sandwich chemoradiation: P-GEMOX (2 cycles) followed by RT 56 Gy followed by P-GEMOX (2-4 cycles)
 - Palliative RT: 20-36 Gy in 5-18 fractions
- *PCMZL and PCFCL*: Optimal initial management for solitary/regional disease is with 24-30 Gy external beam radiation therapy (EBRT)
 - RT for relapsed disease: 4 Gy EBRT may be adequate
- *MF/SS*
 - Treatment of individual plaques or tumors
 - Optimal management for individual plaque and tumor lesions is with EBRT, 8-12 Gy; 8 Gy may be given in 1-2 fractions
 - For unilesional MF, 24-30 Gy
 - Total Skin Electron Beam Therapy (TSEBT) may be utilized to cover the entire cutaneous surface
 - The dose range is 12-36Gy, generally 4 – 6 Gy per week. “Shadowed” areas may need to be supplemented with individual electron fields. Individual tumors may be boost with doses of 4-12 Gy
- *Primary cutaneous ALCL*:
 - RT for curative treatment: 24-36 Gy
 - Palliative RT: 2 Gy x 2
 - Doses as low as 6 Gy are used occasionally, but data are limited regarding response and duration.

TREATMENT OPTIONS (will be reviewed on a case-by-case basis):

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. These requests will be reviewed on a case-by-case basis.

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.

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POLICY HISTORY

Date	Summary
May 2023	<ul style="list-style-type: none">• Clarified/Updated<ul style="list-style-type: none">○ Basal & Squamous Cell Skin Cancer○ Melanoma○ Merkel Cell Carcinoma○ Cutaneous Lymphoma• Deleted Additional Resources• Changed “Treatment options requiring physician review” to Treatment Options (will be reviewed on a case-by-base basis)
January 2022	<ul style="list-style-type: none">• Added Merkel Cell Carcinoma• Added Total Skin Electron Beam Therapy (TSEBT) may be utilized to cover the entire cutaneous surface• Added dosage guidelines for TSEBT

Reviewed / Approved by NIA Clinical Guideline Committee

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*National Imaging Associates, Inc.	
Clinical guidelines: SMALL CELL LUNG CANCER	Original Date: March 2011
Radiation Oncology	Last Revised Date: May 2023
Guideline Number: NIA_CG_123	Implementation Date: January 2024

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.*
- *Where a specific clinical indication is not directly addressed in this guideline, medical necessity determination will be made based on widely accepted standard of care criteria. These criteria are supported by evidence-based or peer-reviewed sources such as medical literature, societal guidelines and state/national recommendations.*

INDICATIONS FOR RADIATION THERAPY

Limited-Stage SCLC (T1-2, N1-N3 M0)¹

- 2D or 3D Conformal Radiation Therapy (3DCRT)
- Two randomized phase III trials did not demonstrate superiority of 66 Gy in 6.5 weeks/2 Gy daily (the European CONVERT trial) or 70 G in 7 weeks/2 Gy daily (CALGB 30610/RTOG 0538) over 45 Gy in 3 weeks/1.5 Gy BID, but overall survival and toxicity were similar²⁻⁴

Dosage Guidelines:

- Up to 30 fractions is medically necessary

Extensive-Stage SCLC (T any, N any, M1a/b)¹

- Consolidative thoracic RT is beneficial for selected patients with ES-SCLC with complete response or good response to systemic therapy, especially with residual thoracic disease and low-bulk extrathoracic metastatic disease
- The Dutch CREST randomized trial of modest-dose thoracic RT (30 Gy in 10 fractions) in patients with ES-SCLC that responded to systemic therapy demonstrated significantly improved 2-year overall survival and 6-month progression-free survival. Benefit of

consolidative thoracic RT is limited to the majority of patients who had residual thoracic disease after systemic therapy^{5,6}

- 2D or 3D Conformal Radiation Therapy (3DCRT) Radiation therapy to treat symptomatic sites or treatment of cord compression

Dosage Guidelines:

- 30 Gy in 10 daily fractions up to definitive dosing regimens in patients with a longer life expectancy.
- Up to 30 fractions is medically necessary

Prophylactic Cranial Irradiation (PCI)

- The benefit of PCI is unclear in patients who have undergone definitive therapy for very early LS-SCLC, i.e., pathologic stage I–IIA (T1–2, N0, M0)⁷
- However, PCI may have a benefit in patients who are found to have pathologic stage IIB or III SCLC after complete resection^{7,8}
- Routine PCI is not indicated for Extensive stage patients.
- PCI is not recommended in patients with poor performance status or impaired neurocognitive function⁹
- Brain MRI surveillance should be performed in patients not receiving PCI⁷

Hippocampal Sparing Intensity Modulated Radiation Therapy for PCI^{1,10,11} **(Will be reviewed on a case-by-case basis)**

- A phase III randomized trial of HA-WBRT versus conventional WBRT demonstrated improved cognitive preservation and patient-reported outcomes with HA-WBRT in patients with brain metastases from mixed histologies¹⁰
- For patients with a better prognosis (e.g., ≥4 months), hippocampal-sparing WBRT using IMRT plus memantine is preferred because it produces less cognitive function failure than conventional WBRT plus memantine¹⁰
- Hippocampal sparing whole brain IMRT (plus memantine) is considered medically necessary for 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

2D or 3D Conformal Radiation Therapy (3DCRT) is indicated for in patients with poor performance status or impaired neurocognitive function.

Dosage Guidelines

- The preferred dose for PCI to the whole brain is 25 Gy in 10 daily fractions.

TREATMENT OPTIONS (to be reviewed on a case-by-case basis)

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 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.

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)^{1, 12-20}

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.²¹ 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.²¹ 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.²¹ 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.

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POLICY HISTORY

Date	Summary
May 2023	<ul style="list-style-type: none"> • Added to Limited Stage SCLC: Two randomized phase III trials did not demonstrate superiority of 66 Gy in 6.5 weeks/2 Gy daily (the European CONVERT trial) or 70 Gy in 7 weeks/2 Gy daily (CALGB 30610/RTOG 0538) over 45 Gy in 3 weeks/1.5 Gy BID, but overall survival and toxicity were similar • Added to Extensive Stage SCLC: <ul style="list-style-type: none"> ○ Consolidative thoracic RT is beneficial for selected patients with ES-SCLC with complete response or good response to systemic therapy, especially with residual thoracic disease and low-bulk extrathoracic metastatic disease. ○ The Dutch CREST randomized trial of modest-dose thoracic RT (30 Gy in 10 fractions) in patients with ES-SCLC that responded to systemic therapy demonstrated significantly improved 2-year overall survival and 6-month progression-free survival. Benefit of consolidative thoracic RT is limited to the majority of patients who had residual thoracic disease after systemic therapy (17, 18). ○ Clarified/updated Dosage Guidelines under Extensive Stage SCLC • Added to PCI <ul style="list-style-type: none"> ○ The benefit of PCI is unclear in patients who have undergone definitive therapy for very early LS-SCLC, i.e., pathologic stage I–IIA (T1–2, N0, M0) ○ However, PCI may have a benefit in patients who are found to have pathologic stage IIB or III SCLC after complete resection ○ Routine PCI is not indicated for Extensive stage patients. ○ PCI is not recommended in patients with poor performance status or impaired neurocognitive function ○ Brain MRI surveillance should be performed in patients not receiving PCI • Moved Hippocampal sparing WBRT up under PCI • Clarified/updated Hippocampal sparing WBRT <ul style="list-style-type: none"> ○ A phase III randomized trial of HA-WBRT versus conventional WBRT demonstrated improved cognitive preservation and patient-reported outcomes with HA-WBRT in patients with brain metastases from mixed histologies ○ For patients with a better prognosis (e.g., ≥4 months), hippocampal-sparing WBRT using IMRT plus memantine is

	<p>preferred because it produces less cognitive function failure than conventional WBRT plus memantine</p> <ul style="list-style-type: none"> ○ Hippocampal sparing whole brain IMRT (plus memantine) is considered medically necessary for individuals with all of the following: (added “required physician review”) <ul style="list-style-type: none"> ▪ 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 ○ 2D or 3D Conformal Radiation Therapy (3DCRT) is indicated for in patients with poor performance status or impaired neurocognitive function. ● Deleted Additional Resources ● Changed “Treatment options requiring physician review” to Treatment Options (will be reviewed on a case-by-case basis)
January 2022	<ul style="list-style-type: none"> ● 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.”



Reviewed / Approved by NIA Clinical Guideline Committee

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*National Imaging Associates, Inc.	
Clinical guideline STEREOTACTIC RADIOTHERAPY (SRS) STEREOTACTIC BODY RADIATION THERAPY (SBRT)	Original Date: May 2011
CPT Codes: 77371, 77372, 77373, G0339, G0340	Last Revised Date: May 2023
Guideline Number: NIA_CG_222	Implementation Date: January 2024

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.*
- *Where a specific clinical indication is not directly addressed in this guideline, medical necessity determination will be made based on widely accepted standard of care criteria. These criteria are supported by evidence-based or peer-reviewed sources such as medical literature, societal guidelines and state/national recommendations.*

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.¹⁻³ 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 types¹:

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

INDICATIONS FOR STEREOTACTIC RADIATION THERAPY (Will be reviewed on a case-by-case basis)

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^{1,3}
- 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.)^{1,3}
- 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).^{1,3} 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^{1,3}
- Pancreatic Tumors:⁴ SBRT is appropriate for pancreatic cancer to treat locally advanced or recurrent disease without evidence of distant metastasis **OR** in patients who are not candidates for induction chemotherapy **OR** to treat a previously irradiated field
- Hepatocellular Carcinoma
 - As a bridge to liver transplantation
 - As an ablative treatment for limited lesions
- Non-Small Cell Lung Cancer and all of the following:^{5,6}
 - Stage I disease; **AND**
 - 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 Cancer⁷⁻¹⁵
 - SBRT is approvable for clinical stage I to IIA (T1-2,N0) Small Cell Lung Cancer who are medically inoperable or refuse surgery.
- SBRT is indicated for prostate cancer (all risk groups excluding node-positive disease)¹⁶

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:
 - Other non-central nervous system cancers unless noted above
 - Lung (unless above criteria is met)
 - Other cancers, including but not limited to, breast, colon, liver
 - Parkinson's disease and other movement disorders (e.g., tremors)
 - Epilepsy
 - Chronic pain syndromes
 - Treatment of functional disorders other than trigeminal neuralgia

- **Oligometastatic Disease¹⁷**
 - 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 (will be reviewed on a case-by-case basis)¹

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POLICY HISTORY

Date	Summary
May 2023	<ul style="list-style-type: none"> • Moved Pancreatic Tumors under INDICATIONS FOR STEREOTACTIC RADIATION THERAPY • Added: “in patients who are not candidates for induction chemotherapy” to pancreatic cancer • Added: SBRT is indicated for prostate cancer (all risk groups excluding node-positive disease) • Added: Hepatocellular Carcinoma <ul style="list-style-type: none"> ○ As a bridge to liver transplantation ○ As an ablative treatment for limited lesions • Added physician clinical review required to “indications for stereotactic radiation therapy” • Deleted Additional Resources • Removed “physician review” language
January 2022	<ul style="list-style-type: none"> • 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)



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