

National Imaging Associates, Inc.*	
Clinical guidelines BONE METASTASES	Original Date: June 2013
Radiation Oncology	Last Revised Date: January 2022
Guideline Number: NIA_CG_126	Implementation Date: January 2023

MEDICALLY NECESSARY INDICATIONS FOR RADIATION THERAPY

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

Good performance status = ECOG less than 3:

- EBRT –Up to 10 fractions for multiple bone metastases

Poor performance status = ECOG 3 or greater or progressive metastatic disease:

- EBRT – Up to 5 fractions

All other treatment regimens require physician review.

TREATMENT OPTIONS REQUIRING PHYSICIAN REVIEW

Intensity modulated radiation therapy (IMRT)

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

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

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

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

Stereotactic Body Radiation Therapy (SBRT)

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

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

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

Proton Beam Radiation Therapy

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

THE FOLLOWING APPLIES TO CMS (MEDICARE) MEMBERS ONLY

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

BACKGROUND

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

POLICY HISTORY

Date	Summary
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
February 2021	<p>1.MEDICALLY NECESSARY INDICATIONS FOR RADIATION THERAPY Deleted:</p> <ul style="list-style-type: none"> • Conventional 2D planning techniques is appropriate for the treatment of bone metastases. • 3D-CRT may be indicated in select cases such as situations of re-treatment, overlapping volumes or adjacent critical structures that are likely to cause complications. Requests for 3D-CRT must be accompanied by supporting clinical rationale. <p>Favorable Risk (Good performance status = ECOG less than 3):</p> <ul style="list-style-type: none"> • EBRT –Up to 10 fractions for multiple bone metastases • EBRT –Up to 14 fractions for spinal cord compression symptoms or single lesion or instances that require a longer fractionated course to minimize patient discomfort (e.g., nausea) (Lutz, 2017). <p>Unfavorable Risk (Poor performance status = ECOG 3 or greater or progressive metastatic disease):</p> <ul style="list-style-type: none"> • EBRT – Up to 5 fractions <p>Requests and supporting rationale for additional fractions can be discussed with a physician reviewer.</p> <p>Updated: 2D or 3D Conformal External Beam Radiation Therapy (EBRT) is appropriate for the treatment of bone metastases</p> <p>Good performance status = ECOG less than 3:</p> <ul style="list-style-type: none"> • EBRT –Up to 10 fractions for multiple bone metastases <p>Poor performance status = ECOG 3 or greater or progressive metastatic disease:</p> <ul style="list-style-type: none"> • EBRT – Up to 5 fractions <p><i>All other treatment regimens require physician review</i></p> <p>2.TREATMENT OPTIONS REQUIRING PHYSICIAN REVIEW</p>

	<p>Deleted: Stereotactic Body Radiation Therapy is not a standard treatment option for the treatment of bone metastasis (Lutz, 2017). A peer review is required with a radiation oncologist.</p> <p>Updated: Stereotactic Body Radiation Therapy (SBRT) for treatment of bone metastasis may be medically necessary to treat previously irradiated field. (Lutz, 2017).</p> <p>SBRT is medically necessary for extracranial oligometastatic disease for an individual with One (1) to Four (4) metastatic lesions when the following criteria are met: (Cheung P,2016; Palma 2018)</p> <ul style="list-style-type: none"> o Good performance status: ECOG less than 3 or Karnofsky Scale greater than or equal to 70% and o Stable systemic disease or reasonable systemic treatment options. <p>3.References Added and Updated</p>
February 2020	Updated references
February 2019	Added and updated references

REFERENCES

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2. Lievens Y, Guckenberger M, Gomez D, et al. Defining oligometastatic disease from a radiation oncology perspective: An ESTRO-ASTRO consensus document. *Radiother Oncol*. Jul 2020;148:157-166. doi:10.1016/j.radonc.2020.04.003

ADDITIONAL RESOURCES

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2. ACR Appropriateness Criteria®: Non-Spine Bone Metastases. American College of Radiology. Updated 2014. Accessed December 16, 2021. <https://acsearch.acr.org/docs/69354/Narrative/>
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Reviewed / Approved by NIA Clinical Guideline Committee

GENERAL INFORMATION

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

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