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| <b>National Imaging Associates, Inc.</b>               |  |
| <b>Clinical guidelines:<br/>COLORECTAL CANCER</b>      | <b>Original Date: March 2011<br/>Page 1 of 7</b> |
| <b>Radiation Oncology</b>                              | <b>Last Review Date: July 2018</b>               |
| <b>Guideline Number: NIA_CG_121</b>                    | <b>Last Revised Date: April 2018</b>             |
| <b>Responsible Department:<br/>Clinical Operations</b> | <b>Implementation Date : January 2019</b>        |

## INTRODUCTION:

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.

Initial Clinical Reviewers (ICRs) and Physician Clinical Reviewers (PCRs) must be able to apply criteria based on individual needs and based on an assessment of the local delivery system.

## INDICATIONS FOR RADIATION THERAPY

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

- **Rectal Cancer**

- Radiation therapy is considered a medically necessary for the following clinical indications: Preoperative or postoperative/adjvant therapy or as primary therapy if tumor inoperable. Radiation therapy should not replace surgical resection
  - 3D Conformal Radiation Therapy recommended. 45 -54 Gy delivered 25 -30 fractions at 1.8 -2.0 Gy per fraction. Boost may be an option. Dosage exceeding 54 Gy may be necessary for un-resectable tumors.
  - 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, 10-20 Gy external beam radiation and/or brachytherapy to a limited volume can be considered soon after surgery but prior to adjuvant chemotherapy.
  - IMRT is not indicated as a standard treatment option and should be reserved for unique situations but may be utilized for re-irradiation of previously treated patients with recurrence. (Requires Physician review)
  - Proton beam is not an approved treatment option for colorectal cancer.

#### **TREATMENT OPTIONS REQUIRING PHYSICIAN REVIEW:**

##### **Intensity Modulated Radiation Therapy (IMRT)**

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

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

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

##### **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.

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

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

### **Pediatric Considerations**

Pediatric patients with cancer require special handling and the expertise of a pediatric oncologist. These patients are most often treated within a protocol defined by a specialty cancer center.

NIA will approve radiation therapy for malignant tumors in pediatric patients if:

- A tissue diagnosis has been made and the histology of the tumor is known to be radiation sensitive.
- The radiation therapy planned is in accordance with an Institutional Review Board-approved protocol.
- The radiation therapy planned is part of an Institutional Review Board-approved Clinical Trial.

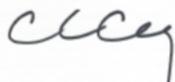
Radiation therapy may be indicated in other instances that will be considered on a case by case basis, as follows:

- If the patient is treated outside of a protocol or clinical trial, the full treatment plan must be submitted for review.
- The treatment plan will be reviewed by a clinician and will be approved when consistent with clinical indications in NIA's Radiation Oncology clinical guidelines and coding standards.
- Treatment plans that are inconsistent with NIA's clinical guidelines and coding standards may still be approved by a physician reviewer based on additional information discussed in a peer-to-peer consultation that provides an appropriate clinical rationale in support of the treatment plan.

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Reviewed / Approved by



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