Rectal Cancer

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**NOTE:** Consider clinical trial when appropriate for eligible patients. For adenomatous polyp with high-grade dysplasia, recommendations are the same as for colon cancer. Refer to colon consensus algorithm.

### EVALUATION

Tumor within 12 cm from anal verge

- Pathology review
- CEA
- Proctoscopic evaluation by surgeon
- High-resolution rectal staging MRI (endorectal ultrasound may be performed if MRI not possible or to facilitate classification of cT1 vs T2 disease)
- CT scan of chest
- Contrast-enhanced CT or MRI of abdomen and pelvis
- Colonoscopy (with biopsy if no pathology or pathology nondiagnostic)

### PRIMARY TREATMENT

1. **Stage I eligible for TAE or TAMIS/TEM resection**
2. **Excision complete?**
   - Yes:
     - Radical surgical resection: LAR, CAA or APR, with or without temporary fecal diversion (ileostomy)
   - No:
     - Neoadjuvant chemoradiation therapy (consider clinical trial if available)

3. **Stage II and Stage III**

- **Multidisciplinary management including medical oncology, surgical oncology, radiation oncology, and GI endoscopy.**
- **Consider adjuvant chemotherapy** (consider clinical trial if available)

4. **Unresectable primary, no metastasis**

- Multidisciplinary management including surgeon, medical oncologist, and radiation oncologist recommended
- Refer to Principles of Rectal Surgery, Chemotherapy and Radiation Therapy on pages 4-8
- Choice and timing of systemic chemotherapy, consideration of surgery, and radiation, are to be individualized based on multidisciplinary management discussion between the medical oncologist, surgeon and radiation oncologist. In all cases, surgical resection should be performed with the intent for cure rather than palliation.

5. **Metastatic disease, intact primary**

- First line chemotherapy with/without chemoradiation, refer to page 3
- If symptomatic, consider chemoradiation therapy, endoscopic intervention (e.g. endoscopic ablation), resection of primary tumor or diverting colostomy

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1. **Criteria for eligibility for transanal excision:** cT1 (EUS or MRI), less than 3cm, low grade, no LVI or PNI.
2. **LAR** = low anterior resection
   **TAE** = transanal excision
   **APR** = abdominoperineal resection
   **TAMIS** = transanal minimally invasive surgery
   **CAA** = colorectal anastomosis
   **TEM** = transanal endoscopic microsurgery

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Department of Clinical Effectiveness V9
Approved by The Executive Committee of the Medical Staff on 11/24/2015
Evaluation and Management of Suspected or Documented Recurrent Rectal Cancer

Elevated CEA or other findings that suggest recurrent disease

- Contrast-enhanced CT of chest and contrast-enhanced CT or MRI of abdomen and pelvis
- Pathology review

**Is recurrence resectable?**

- **Yes**
  - Multidisciplinary management including surgeon, medical oncologist, and radiation oncologist recommended.
  - Type and sequence of chemotherapy, surgery and/or radiation therapy should be individualized to patient based on multidisciplinary review. In all cases, surgical resection should be performed with the intent for cure rather than as palliation.

- **Negative**
  - Consider PET/CT scan, if positive consider biopsy
  - **Recurrence not confirmed**
    - Individualized surveillance
  - **Recurrence confirmed**

- **Positive**
  - Consider PET/CT scan, if positive consider biopsy

**Distant Metastases**

- Yes
  - **Continue current chemotherapy regimen until progression of disease followed by second line chemotherapy if tolerating therapy and ECOG performance status less than or equal to 2.**

- No
  - **Consider adjuvant chemotherapy**

**Local Recurrence**

- First line systemic chemotherapy or Palliative care

**Surgically resectable?**

- **Yes**
  - Consider intraoperative radiotherapy

- **No**
  - Consider adjuvant chemotherapy

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1. Capecitabine or 5-Fluorouracil/leucovorin or 5-Fluorouracil/leucovorin/oxaliplatin based on multidisciplinary review
2. ECOG = Eastern Cooperative Oncology Group

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**CHEMOTHERAPY FOR ADVANCED OR METASTATIC DISEASE**

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### First – Line Therapy

- FOLFOX with or without bevacizumab¹ or
- CapeOx with or without bevacizumab³,⁴ or
- CapeOx with or without panitumumab²

### Second – Line Therapy

- FOLFIRI plus bevacizumab

### Third – Line (plus) Therapy

- Irinotecan or FOLFIRI with or without anti-EGFR therapy² or
- Single-agent anti-EGFR therapy²

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1. Bevacizumab used in combination with IV 5-FU-based chemotherapy is approved for first-line therapy. Elderly patients with a prior arterial thrombotic event are at increased risk of stroke, myocardial infarct and other arterial events. The incidence of venous thrombosis is statistically significant in colorectal cancer patients.

2. A RAS mutation indicates resistance to cetuximab and panitumumab.

3. Patients with diminished creatinine clearance 30-50 mL/minute will require dose reduction. All patients with a creatinine clearance of less than 30 mL/minute will not be eligible to receive capecitabine.

4. If the patient is taking warfarin or phenytoin while on capecitabine, the patient must be monitored regularly due to potential drug-drug interaction.

5. Best suited for surgically resectable patients. Once progresses, consider:
   - Clinical Trial
   - RAS WT: irinotecan or FOLFIRI plus cetuximab or panitumumab
   - Regorafenib

6. A treatment option for patients not able to tolerate oxaliplatin or irinotecan.

7. Consider regimen only in patients with adequate ECOG. Check blood counts regularly. May be best used for neoadjuvant therapy.

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**CHEMOTHERAPY FOR ADVANCED OR METASTATIC DISEASE**

### CapeOx (XELOX)
- Oxaliplatin 100-130 mg/m² IV on Day 1
- Capecitabine 850-1000 mg/m² po twice daily for 14 days
- With or without bevacizumab (7.5 mg/kg IV)
- Repeat every 3 weeks
- With or without panitumumab (9mg/kg every 3 weeks)

### mFOLFOX 6
- Oxaliplatin 85 mg/m² IV over 2 hours on Day 1
- Leucovorin 400 mg/m² IV over 2 hours on Day 1
- 5-Fluorouracil 400 mg/m² IV bolus on Day 1, then 5-Fluorouracil 2400 mg/m² over 46 hours IV continuous infusion
- With or without bevacizumab (5 mg/kg IV)
- Repeat every 2 weeks
- With or without panitumumab (6mg/kg every 2 weeks) or cetuximab

### mFOLFIRI
- Irinotecan 180 mg/m² over 90 minutes on Day 1
- Leucovorin 400 mg/m² over 2 hours during irinotecan on Day 1
- 5-Fluorouracil 400 mg/m² IV bolus, then 5-Fluorouracil 2,400 mg/m² over 46 hours IV continuous infusion
- With or without bevacizumab (5 mg/kg IV)
- Repeat every 2 weeks
- With or without cetuximab (400 mg/m² in first infusion followed by 250 mg/m2 weekly or 500 mg/m² IV every 2 weeks) or panitumumab (6mg/kg every 2 weeks)

### 5-Fluorouracil, Leucovorin or Capecitabine
- Capecitabine 1000 mg/m² po twice daily for 14 days, every 3 weeks
- With or without bevacizumab (7.5 mg/kg IV every 3 weeks)
- Leucovorin 400 mg/m² IV over 2 hours on Day 1
- 5-Fluorouracil 400 mg/m² on Day 1, then 2400 mg/m² over 46 hours IV continuous infusion
- With or without bevacizumab (5 mg/kg IV). Repeat every 2 weeks.

### Irinotecan
- Irinotecan 180 mg/m² IV over 90 minutes on Day 1. Repeat every 2 weeks.
- Irinotecan 300-350 mg/m² IV over 90 minutes on Day 1. Repeat every 3 weeks.

### Anti-EGFR plus Irinotecan
- Cetuximab 400 mg/m² first infusion, then 250 mg/m² weekly
- Cetuximab 350 mg/m² IV every 3 weeks or 180 mg/m² IV every 2 weeks.
- Cetuximab 500 mg/m² every 2 weeks or panitumumab (6mg/kg every 2 weeks)
- With or without irinotecan 180 mg/m² IV every 2 weeks.

### Panitumumab
- Panitumumab 6 mg/kg IV every 2 weeks.
- Panitumumab 9 mg/kg IV every 3 weeks.

### Regorafenib
- Regorafenib 160 mg po daily for 21 days then 1 week off, one cycle is every 28 days.
  (Recommend to start at 120 mg po daily for 21 days then 1 week off for the first one – two months, then dose escalate as appropriate)

### FOLFOXIRI
Consider dosing as FOLFIRINOX for toxicity
- Oxaliplatin 85 mg/m² IV Day 1
- Irinotecan 180 mg/m² IV Day 1
- 5-Fluorouracil 2400 mg/m² IV continuous infusion over 46 hours. Repeat every 2 weeks.

---

1 A RAS mutation indicates resistance to cetuximab and panitumumab. (See references for principles of chemotherapy on page 12)

2 Consider regimen only in patients with adequate ECOG. Check blood counts regularly. May be best used for neoadjuvant therapy
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**OBSERVATION/SURVEILLANCE**

<table>
<thead>
<tr>
<th>Stage</th>
<th>Physical exam</th>
<th>CEA</th>
<th>CT scan of chest and contrast-enhanced CT or MRI of abdomen/pelvis</th>
<th>Colonoscopy</th>
</tr>
</thead>
<tbody>
<tr>
<td>I</td>
<td>every 6-12 months for 3 years</td>
<td>every 6-12 months for 3 years</td>
<td>every 12 months for 3 years</td>
<td>at one year then (if normal), after 3 more years, and then once every 5 years.</td>
</tr>
<tr>
<td>II: (low risk)</td>
<td>every 3 - 6 months for 2 years, then every 6 months for 3 years</td>
<td>every 3-6 months for 2 years, then every 6 months for 3 years</td>
<td>every 12 months for 5 years</td>
<td>at one year then (if normal) after 3 more years and then once every 5 years.</td>
</tr>
<tr>
<td>II: (high risk) and Stage III</td>
<td>every 3-4 months for 3 years, then every 6 months for 2 years</td>
<td>every 3-4 months for 3 years, then every 6 months for 2 years</td>
<td>every 12 months for at least 5 yrs</td>
<td>at one year then (if normal), after 3 more years, and then once every 5 years.</td>
</tr>
<tr>
<td>IV - NED</td>
<td>every 3 - 4 months for 2 years, then every 6 months for 3 years</td>
<td>every 3-4 months for 2 years, then every 6 months for 3 years</td>
<td>every 3-4 months for 2 years, every 6 months for 2 years, then annually after 5 years</td>
<td>At one year from rectal resection then (if normal), after 3 more years, and then once every 5 years.</td>
</tr>
<tr>
<td>IV</td>
<td>Individualized if on therapy</td>
<td>Physical exam: every 3-4 months for 2 years, then every 6 months for 3 years</td>
<td>CT of chest and contrast-enhanced CT or MRI of abdomen/pelvis: every 3 months.</td>
<td>Colonoscopy: Patients with unresected, intact primary tumors, endoscopic surveillance is recommended every 4-6 months to ensure luminal patency.</td>
</tr>
</tbody>
</table>

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1. NOTE: Surveillance imaging with PET/CT alone is not recommended as primary imaging modality when there is no contraindication to conventional contrast-enhanced CT scan.
2. When surgical resection has been performed according to the principals outlined, patients with good pathological response to neoadjuvant chemoradiation are at low risk and routine proctoscopic evaluation may be selectively omitted.
3. NED: No evidence of disease
PRINCIPLES OF RECTAL SURGERY

Transanal Excision: (Including Transanal Minimally Invasive Surgery (TAMIS) or Transanal Endoscopic Microsurgery (TEM))

Criteria (must meet all)
- T1N0 staging on ultrasound or high resolution MRI and cross-sectional imaging
- Less than 30% circumference
- Able to completely remove tumor with 1 cm margin (full-thickness)
- Well- to moderately- differentiated histology
- No lymphovascular invasion
- Less than 3 cm in greatest dimension
- No perineural invasion

Transabdominal Resection: (Low anterior resection or coloanal anastomosis using total or tumor-specific mesorectal excision.)

General Management Principles
- The treating surgeon should perform an endoscopic evaluation (e.g. proctosigmoidoscopy) before initiating treatment in order to assess the full extent of primary tumor involvement.
- Primary tumor resection should include adequate margins of resection and be en bloc with the mesorectum and involved adjacent viscera. Tumor transection or resection that leaves gross residual tumor in the operative field (R2) should be avoided.
- Treatment of draining lymphatics is accomplished by en bloc resection of both the proximally ascending and distally descending nodal basins.
- Function restorative reconstruction (e.g. sphincter preservation) performed when possible and deemed appropriate based on an assessment of the underlying functional status of the anal sphincter.

Distal and Circumferential Resection Margins
- The distal resection margin should not be involved by tumor and ideally be greater than 1 cm below the distal extent of the tumor when a total mesorectal excision has been performed.
- Intramural tumor spread may be present up to 1-2 cm distal to the tumor.
- Determination of the level of distal transection should be based on the level of tumor involvement prior to neoadjuvant therapy.
- In cases of proximal rectal location, the distal margin of resection should be at least 4-5 cm below the distal extent of the tumor en bloc with the mesorectum (see lymphadenectomy principles below).
- Full rectal mobilization allows for a negative distal margin and adequate mesorectal excision.
- A negative circumferential resection margin (greater than 1 mm on microscopic evaluation) should be obtained (R0). Resection margins less than or equal to 1 mm should be considered microscopically positive (R1) and will be at higher risk for recurrence.

Lymphadenectomy and Mesorectal Excision
- Routine radical lymphadenectomy should be achieved with proximal lymphovascular resection to the origin of the superior hemorrhoidal vessels (include IMA level lymph nodes when clinically suspected to be involved) and distal complete mesorectal excision to include the entire mesorectum or the tumor-specific mesorectum at least 5 cm below the distal extent of the tumor (so called "tumor specific mesorectal excision).”
- The mesorectal dissection should be performed sharply within the mesorectal fascial plane to ensure a complete mesorectal excision.
- Clinically suspicious nodes beyond the field of resection should be biopsied or removed if possible.
- Resection of lateral lymph nodes (internal iliac and obturator lymph node basins) should be considered in the presence of clinically suspected nodes.

Total mesorectal excision (TME)
- A minimally invasive approach (e.g. laparoscopic or robotic) should adhere to the same principles of cancer surgery as for open resection.
Transabdominal Resection: (continued)

Abdominoperineal Resection
- Tumors located in the distal rectum requiring an abdominoperineal resection are at an increased risk for circumferential resection margin positivity.
- In addition to the TME principles as outlined above, the division of the pelvic floor (levator muscles) should be wide around the level of tumor to avoid narrowing or coning of the resection. For anterior or posterior tumors, this could require en bloc resection of the adjacent structure such as the vagina or coccyx in order to ensure a clear margin.
- The approach to the pelvic floor may be trans-abdominal (from above) or transperineal (from below) in either a lithotomy or prone position as long as a complete resection with clear margins can be achieved.

Liver
- Complete resection or ablative therapy must be feasible based on anatomic grounds and extent of disease. Maintenance of normal hepatic function is required.
- Resectable extrahepatic sites of metastases do not preclude curative hepatic resection.
- Re-evaluation for resection can be considered in otherwise unresectable patients after neoadjuvant therapy. All original sites of disease must be resectable.
- Hepatic resection is the treatment of choice for resectable liver metastases from colorectal cancer.
- Ablative techniques may be considered in conjunction with resection in otherwise unresectable patients.
- Primary tumor should be resected with curative intent (R0). Consider completion with radical lymphadenectomy at time of liver resection if synchronous metastasis at presentation and a non-oncologic resection of the primary was performed.
- Prior resection does not preclude re-resection in selected patients.

Lung
- Complete resection must be feasible based on anatomic grounds and the extent of disease. Maintenance of adequate residual pulmonary function is required.
- Resectable extrapulmonary metastases do not preclude resection.
- Primary tumor should be resected with curative intent (R0).
- Prior resection does not preclude a subsequent resection in selected patients.

Other Sites (Other than Liver or Lung)
- Resection of isolated metastasis outside of the liver or lung may be considered if complete resection can be performed but treatment should be individualized and based on a multidisciplinary treatment plan.
- Peritoneal Carcinomatosis
  - Cytoreductive surgery with or without intra-peritoneal hyperthermic chemotherapy may be considered in the setting of a clinical trial.
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PRINCIPLES OF NEOADJUVANT CHEMORADIATION THERAPY

Ideally, neoadjuvant chemoradiation therapy is provided to the patient prior to surgical resection followed by adjuvant chemotherapy. However, in select situations where surgery was initially provided, adjuvant chemoradiation therapy is then considered followed by adjuvant chemotherapy.

Dosing Schedule for concurrent chemotherapy and radiotherapy:
- Radiotherapy plus infusional 5-Fluorouracil 250 - 300 mg/m2/day IV continuous infusion, Monday thru Friday on days of radiation therapy.
- Radiotherapy plus capecitabine 825 mg/m2 PO twice daily, Monday thru Friday on days of radiation therapy.

PRINCIPLES OF ADJUVANT THERAPY

Postoperative adjuvant chemotherapy for patients receiving preoperative chemotherapy/radiation therapy:

mFOLFOX 6
- Oxaliplatin 85 mg/m2 IV over 2 hours on Day 1.
- Leucovorin 400 mg/m2 IV over 2 hours on Day 1.
- 5-FU 400 mg/m2 IV bolus on day 1, then 2400 mg/m2 IV over 46 hours continuous infusion.
- Repeat every 2 weeks.

Capecitabine 1000 mg/m2 PO twice daily on days 1-14, followed by 7 days rest.
- Repeat every 3 weeks.

CapeOx (XELOX)
- Oxaliplatin 100-130 mg/m2 IV on Day 1
- Capecitabine 850-1000 mg/m2 PO twice daily on days 1-14, followed by 7 days rest
- Repeat every 3 weeks

Infusional 5-Fluorouracil/leucovorin
- Leucovorin 400 mg/m2 IV over 2 hours on Day 1.
- 5-FU 400 mg/m2 IV bolus on Day 1, the 2400 mg/m2 IV over 46 hours continuous infusion.
- Repeat every 2 weeks.
PRINCIPLES OF RADIATION THERAPY

- Radiation therapy fields should include the tumor, the presacral nodes, the mesorectal region and the internal iliac nodes.

- Multiple radiation therapy fields should be used (generally a 3 or 4 field technique). Positioning and other techniques to minimize the volume of small bowel in the fields should be encouraged.

- For postoperative patients treated by abdominoperineal resection, the perineal scar should be included within the fields.

- Radiation doses: 45 Gy in 25 fractions to the pelvis, followed by a boost to the tumor bed and presacral region, with a dose of 5.4 Gy in 3 fractions for preoperative treatments, and a dose of 5.4-9 Gy in 3-5 fractions for postoperative treatments.

- IORT (intraoperative radiation therapy), if available, should be considered for very close or positive margins after resection, as an additional boost, especially for patients with T4 or recurrent cancers.

- For unresectable cancers, doses higher than 54 Gy may be required.

- 5-fluorouracil based chemotherapy should be delivered concurrently with radiation.

- IMRT may be considered in selected cases to reduce toxicity. For IMRT cases, careful attention should be given to appropriate contouring, such as that recommended by the RTOG consensus panel.
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SUGGESTED READINGS


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**SUGGESTED READINGS**


Lenz et al. (2014). CALGB/SWOG 80405: Phase III trial of FOLFIRI or mFOLFOX6 with bevacizumab or cetuximab for patients with expanded RAS analyses in untreated metastatic adenocarcinoma of the colon or rectum; ESMO.


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DEVELOPMENT CREDITS

This practice consensus algorithm is based on majority expert opinion of the Gastrointestinal work group Faculty at the University of Texas MD Anderson Cancer Center. It was developed using a multidisciplinary approach that included input from the following medical, radiation and surgical oncologists.

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