AMERICAN COLLEGE OF SURGEONS

Optimal Resources for Rectal Cancer Care 2026 STANDARDS

Effective January 2026

AMERICAN COLLEGE OF SURGEONS SURGICAL QUALITY

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Rectal Cancer Accreditation

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AMERICAN COLLEGE OF SURGEONS

Optimal Resources for Rectal Cancer Care

2026 Standards

Effective January 2026

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Important Information

These standards are intended solely as qualification criteria for National Accreditation Program for Rectal Cancer (NAPRC) accreditation. They do not constitute a standard of care and are not intended to replace the medical judgment of any physician or health care professional in individual or general circumstances.

"Standard" as used in *Optimal Resources for Rectal Cancer Care (2026 Standards)* is defined as a "qualification for accreditation," not standard of care.

In order for a program to be found compliant with the NAPRC Standards, the program must be able to demonstrate compliance with the entire standard as outlined in the **Definition and Requirements, Documentation,** and **Measure of Compliance** sections under each standard. The **Documentation** and **Measure of Compliance** sections under each standard are intended to provide summary guidance on how compliance must be demonstrated but are not intended to stand alone or supersede the **Definition and Requirements.**

In addition to verifying compliance with the standards as written and outlined in *Optimal Resources for Rectal Cancer Care (2026 Standards)*, the NAPRC may also consider additional administrative factors when reviewing a program for accreditation. The NAPRC reserves the right to withhold accreditation based on such factors. Examples include, but are not limited to: non-payment of accreditation invoices and outstanding fees, failure to schedule or complete an accreditation site visit in a timely manner, failure to properly remit any or all contracts and contractual obligations related to NAPRC accreditation.

Confidentiality Requirements

The American College of Surgeons (ACoS) and the National Accreditation Program for Rectal Cancer (NAPRC) expect NAPRC-accredited programs to follow local, state, and federal requirements related to patient privacy, risk management, and peer review in complying with or providing information to demonstrate compliance with standards of accreditation. These requirements vary from state-to-state.

Acknowledgments

The National Accreditation Program for Rectal Cancer (NAPRC) is thankful to the members of the NAPRC Committees for their efforts to improve the care and treatment of patients with rectal cancer in the United States.

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About the National Accreditation Program for Rectal Cancer

Background

The National Accreditation Program for Rectal Cancer (NAPRC) was developed through collaboration between the OSTRiCh Consortium (Optimizing the Surgical Treatment of Rectal Cancer) and the Commission on Cancer (CoC), a quality program of the American College of Surgeons (ACoS). During the last 20 years, the outcomes of rectal cancer have repeatedly been shown to be tremendously variable and highly contingent upon specialization, training, and volume. Some of these very important and highly statistically significant variations relate to rates of postoperative mortality, incidence of local recurrence, incidence of construction of permanent colostomy, and five-year survival. These variations have been confirmed in the United States. Baek noted that patients in the state of California were as likely to be operated upon at a low-volume as a medium-volume or high-volume hospital. There were highly significant differences in favor of high-volume hospitals relative to mortality and rates of sphincter preservation.

Ricciardi assessed 20,000 proctectomies undertaken between 2002 and 2004 and analyzed county data in 21 states. Fifty percent (50%) of patients underwent construction of permanent stoma and only twenty percent (20%) of the 21 counties offered colostomy rates less than forty percent (40%). This same problem had existed in Europe, but through numerous initiatives in Sweden, Denmark, Spain, Belgium, the Netherlands, Norway, and the United Kingdom, outcomes have been improved. Specific measurable improvements have been noted in the rates of complete total mesorectal excision, the rates of permanent stoma construction, the incidence of local recurrence, and overall survival.

Based on the significant variability in the United States and the fact that a number of European countries were able to, on a national level, improve the quality of rectal cancer care, the OSTRiCh Consortium convened in 2011. Since that time the OSTRiCh Consortium has performed several analyses, culminating in a series of publications highlighting the problem of tremendous variability of rectal cancer care on a national level in the United States.

The OSTRiCh Consortium reported these findings to the Accreditation Committee of the Commission on Cancer and the officers and regents of the American College of Surgeons. Thereafter, the NAPRC was developed.

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Standards Interpretation

NAPRC-accredited programs must understand, implement, and demonstrate compliance with the accreditation standards outlined in *Optimal Resources for Rectal Cancer Care (2026 Standards)* as written and defined by the NAPRC. While a full glossary of terms is provided at the end of this manual, it is important to establish definitions for several of these key terms prior to reading the accreditation standards.

Accredited Program(s): A medical institution providing comprehensive multidisciplinary care for patients with rectal cancer, which has achieved accreditation by the National Accreditation Program for Rectal Cancer (NAPRC). This also refers to initial applicant programs that are actively pursuing accreditation with the NAPRC.

Calendar year review: Compliance criteria requiring annual review must be completed at least once for each full calendar year (January 1 – December 31).

Protocol: Previously referred to as "policies and procedures" in past versions of the NAPRC Standards, a protocol is a structured and consistent process crafted by the NAPRC-accredited program to help implement the required compliance criteria for specific NAPRC standards. Protocols must be written and documented in a manner that demonstrates compliance with whichever NAPRC standard the protocol is designed to address. Additionally, all protocols must be formally approved by the Rectal Cancer Multidisciplinary Team (RC-MDT). Protocols do not need to be officially recognized hospital or institutional policies. **Please refer to the NAPRC 2026 Standards FAQ for guidelines and recommendations related to the development of protocols.**

It is the responsibility of all NAPRC-accredited programs to read *Optimal Resources for Rectal Cancer Care (2026 Standards)* in its entirety and demonstrate compliance with all applicable requirements for all applicable standards. In order for a program to be found compliant with the NAPRC Standards, the program must be able to demonstrate compliance with the entire standard as outlined in the **Definition and Requirements, Documentation,** and **Measure of Compliance** sections under each standard. The **Documentation** and **Measure of Compliance** sections under each standard are intended to provide summary guidance on how compliance must be demonstrated but are not intended to stand alone or supersede the **Definition and Requirements**.

Accreditation Process

Processes for accreditation are detailed and updated on the <u>NAPRC website</u> and within the <u>Quality Portal</u>. The National Accreditation Program for Rectal Cancer (NAPRC) reserves the right to revise accreditation processes as needed.

Accreditation Awards

Compliance ratings for each standard are decided based on consensus by the assigned NAPRC Site Reviewer and the NAPRC staff. When required, the NAPRC Executive Reviewers will also contribute to the compliance rating decision as the final adjudicators.

Each standard is rated as "Compliant," "Non-Compliant," or "Not Applicable."

Accreditation Status	Definition
Accredited	Awarded when a program has completed the site visit process and demonstrated full compliance with all applicable standards. Accredited outcomes: • Program appears on the <u>"Find an Accredited Program"</u> website • Program has full access to the <u>Quality Portal</u> and its related resources • Certificate of accreditation is awarded
Accredited – Corrective Action Required Renewal Programs Only	 Awarded when a renewal program receives a non-compliant rating for at least one (1) applicable standard, but no more than six (6) of all applicable standards, rated during the site visit process. Corrective Action outcomes: Program has twelve (12) months from the date of the accreditation report to resolve all non-compliant standards ratings Program appears on the <u>"Find an Accredited Program"</u> website Program has full access to the <u>Quality Portal</u> and its related resources Certificate of accreditation is awarded after all non-compliant standards ratings have been resolved and Accredited status has been achieved
Not Accredited – Corrective Action Required	 Awarded when an initial applicant receives a non-compliant rating for six (6) or fewer applicable standards rated during the site visit process. Not Accredited Corrective Action outcomes: Program has twelve (12) months from the date of the accreditation report to resolve all non-compliant standards ratings Program does not appear on the <u>"Find an Accredited Program"</u> website Program has full access to the <u>Quality Portal</u> and its related resources Certificate of accreditation is awarded after all non-compliant standards ratings have been resolved and Accredited status has been achieved
Not Accredited	 Awarded when a renewal program receives a non-compliant rating for seven (7) or more of the applicable standards rated during the site visit process. Awarded when an initial applicant receives a non-compliant rating for seven (7) or more applicable standards rated during the site visit process. Awarded when any program does not resolve all non-compliant standards within the established timeframe for corrective action. Not Accredited outcomes: Program does not appear on the <u>"Find an Accredited Program"</u> website Program does not have access to the <u>Quality Portal</u> Program may re-apply for accreditation as an initial applicant after documenting one (1) calendar year of compliance with all applicable standards

NAPRC Patient Care Algorithms

Surgical Resection with/without Neoadjuvant Therapy



Treatment	Applicable NAPRC Standards											
	5.2	5.3	5.4	5.5	5.6	5.7	5.8	5.9	5.10	5.11	5.12	5.13
Surgery	\checkmark	\checkmark	\checkmark	\checkmark	\checkmark	\checkmark	\checkmark	\checkmark	\checkmark	\checkmark		
Neoadjuvant Therapy $ ightarrow$ Surgery	\checkmark	\checkmark	\checkmark	\checkmark	\checkmark	\checkmark	\checkmark	\checkmark	\checkmark	\checkmark	\checkmark	
Neoadjuvant Therapy $ ightarrow$ Watch and Wait	\checkmark	\checkmark	\checkmark	\checkmark	\checkmark	\checkmark				\checkmark	\checkmark	\checkmark

NAPRC Patient Care Algorithms

Local Excision with/without Neoadjuvant Therapy



NAPRC Patient Care Algorithms

Local Excision with/without Neoadjuvant Therapy

Treatment	Applicable NAPRC Standards											
	5.2	5.3	5.4	5.5	5.6	5.7	5.8	5.9	5.10	5.11	5.12	5.13
Local Excision – Incomplete Removal \rightarrow Neoadjuvant Therapy	\checkmark	\checkmark	\checkmark	\checkmark	\checkmark	\checkmark				\checkmark	\checkmark	\checkmark
Local Excision – Incomplete Removal \rightarrow Surgery or Re-Excision	\checkmark	\checkmark	\checkmark	\checkmark	\checkmark	\checkmark	\checkmark	\checkmark	\checkmark	\checkmark		
Local Excision – Complete Removal → No High-Risk Features												
Local Excision – Complete Removal → High Risk → No Further Treatment	\checkmark	\checkmark	\checkmark	\checkmark	\checkmark					\checkmark		
Local Excision – Complete Removal → High Risk → Neoadjuvant Therapy	\checkmark	\checkmark	\checkmark	\checkmark	\checkmark	\checkmark				\checkmark	\checkmark	\checkmark
Local Excision – Complete Removal \rightarrow High Risk \rightarrow Surgery or Re-Excision	\checkmark	\checkmark	\checkmark	\checkmark	\checkmark	\checkmark	\checkmark	\checkmark	\checkmark	~		



1

Institutional Administrative Commitment

Rationale

Institutional commitment is essential for the development and success of a National Accreditation Program for Rectal Cancer (NAPRC) program. Resource allocation (such as equipment, personnel, and administrative support), a dedication to patient safety, and an enduring focus on continuous quality improvement are the hallmarks of strong institutional administrative support which help facilitate success.

1.1 Administrative Commitment

Definition and Requirements

The NAPRC-accredited program must provide a letter of authority from facility leadership (CEO or equivalent) demonstrating commitment to the rectal cancer program, which includes, but is not limited to:

- A high-level description of the NAPRC-accredited program
- Any initiatives involving the NAPRC-accredited program during the accreditation cycle that were initiated for the purposes of quality and safety
- Facility leadership's involvement in the NAPRC-accredited program
- A statement of attestation committing to healthcare equity
- Examples of current and future initiatives promoting equitable and inclusive healthcare practices and a culture of safety for providers and patients
- Examples of current and future financial investment in the NAPRC-accredited program

Documentation

Submitted with Pre-Review Questionnaire

• Letter of authority from facility leadership that includes all required elements

Measure of Compliance

Once each accreditation cycle, the NAPRC-accredited program fulfills all compliance criteria:

• Rectal cancer program authority is established and documented by the facility through a letter from facility leadership that includes all required elements

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2

Program Scope and Governance

Rationale

The Rectal Cancer Multidisciplinary Team (RC-MDT) provides the structure, process, and personnel to obtain and maintain the National Accreditation Program for Rectal Cancer standards. This includes the leadership who provide cohesion in the structure of the program.

2.1 Rectal Cancer Multidisciplinary Care

Definition and Requirements

Cancer outcomes are better when patients are managed according to the principles of multidisciplinary team (MDT) care. There is increasing evidence that MDTs are associated with improved clinical decision making, clinical outcomes, and patient experience in several cancer types, including rectal. Implementation of an MDT approach to rectal cancer care in several European countries has resulted in lower rates of permanent stoma, reduced rates of local recurrence, greater delivery of evidence-based care, and improved overall survival.

The NAPRC-accredited program must establish a Rectal Cancer Multidisciplinary Team (RC-MDT). The RC-MDT must include at least one appointed physician member from each of the following specialties: surgery, pathology, radiology, medical oncology, and radiation oncology. A lead physician must be appointed for each of the following specialties: pathology, radiology, medical oncology, and radiation oncology.

NAPRC-accredited programs may choose to appoint more than one required member from each specialty to the RC-MDT. Each of the following specialties may appoint up to eight (8) physicians to the RC-MDT: pathology, radiology, radiation oncology, and medical oncology. All surgeons (excluding fellows and residents) who perform rectal cancer surgery at the facility must be members of the RC-MDT.

Additional required members of the RC-MDT are the Rectal Cancer Program (RCP) Director, outlined in Standard 2.2, and the Rectal Cancer Program (RCP) Coordinator, outlined in Standard 2.3. Compliance with Standard 2.1 is evaluated based on the outlined requirements for the establishment of the RC-MDT. Compliance with the RCP Director and RCP Coordinator roles are evaluated in Standards 2.2 and 2.3.

The RC-MDT must maintain accurate meeting minutes, including documentation of meeting attendance for all appointed members. Requirements for individual attendance at RC-MDT meetings are outlined in Standard 2.5. Membership appointments to the RC-MDT must occur at least once during each accreditation cycle. These appointments must occur during the first meeting of any calendar year. All appointments must be documented in the RC-MDT meeting minutes. If an appointed member cannot continue to serve on the RC-MDT, it must be documented in the RC-MDT meeting minutes.

It is recommended that RC-MDT meetings are held separately from other cancer site multidisciplinary meetings. However, at the discretion of the NAPRC-accredited program, RC-MDT meetings may be held in conjunction with another cancer site(s) as long as the required RC-MDT members and specialties are present and the RC-MDT meeting meets the measures of compliance for all applicable NAPRC standards.

Documentation

Submitted with Pre-Review Questionnaire

• RC-MDT meeting minutes

Measure of Compliance

The NAPRC-accredited program fulfills all compliance criteria:

- A defined RC-MDT roster is established and documented in the RC-MDT meeting minutes
- The RC-MDT roster meets the following requirements:
 - At least one appointed physician member from each of the following specialties: surgery, pathology, radiology, medical oncology, and radiation oncology
 - A lead physician appointed for each of the following specialties: pathology, radiology, medical oncology, and radiation oncology
 - All surgeons (excluding fellows and residents) who perform rectal cancer surgery at the facility are members of the RC-MDT
 - No more than eight (8) physicians from the following specialties are appointed to the RC-MDT: pathology, radiology, radiation oncology, and medical oncology

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2.2 Rectal Cancer Program Director

Definition and Requirements

The NAPRC-accredited program must appoint an RCP Director who chairs the Rectal Cancer Multidisciplinary Team (RC-MDT). The RCP Director serves as the chair of the RC-MDT and as a liaison to the NAPRC facility's Commission on Cancer (CoC) committee. The RCP Director must be an active physician member of the medical staff at the NAPRCaccredited facility and must be involved in the management and care of patients with rectal cancer. The appointment of co-RCP Directors is permissible. The decision to appoint co-RCP Directors is at the discretion of the NAPRC-accredited program.

The appointment of the RCP Director, or RCP co-Directors, must take place at least once during each accreditation cycle at the first meeting of any calendar year and must be documented in the RC-MDT meeting minutes. If co-Directors are appointed, both must individually meet the RC-MDT meeting attendance requirements outlined in Standard 2.5. If the RCP Director cannot continue to serve on the RC-MDT, a new, qualified physician must be appointed as the RCP Director at the next RC-MDT meeting, and the appointment must be documented in the RC-MDT meeting minutes.

Internal Audit Responsibilities

The RCP Director is responsible for overseeing RC-MDT activity. As required under the **Internal Medical Record Review** section for each standard in Chapter 5, the RCP Director is responsible for overseeing internal audits of the NAPRC-accredited program's performance and the development of any necessary action plans.

The RCP Director may delegate responsibility for specific audits and any necessary action plans to appropriately credentialed physician members of the RC-MDT.

CoC Committee Liaison Responsibilities

Each calendar year, the RCP Director must attend one (1) of the NAPRC facility's CoC committee meetings and present a report on the activities of the NAPRC-accredited program. At a minimum, the RCP Director's report must include the results of the internal audits required for each standard in Chapter 5.

Documentation

Submitted with Pre-Review Questionnaire

- RC-MDT meeting minutes
- CoC committee meeting minutes documenting the RCP Director's report to the CoC committee

Measure of Compliance

The NAPRC-accredited program fulfills all compliance criteria:

- The RCP Director is appointed at least once during each accreditation cycle at the first meeting of any calendar year, with documentation in the RC-MDT meeting minutes
- The results of all Chapter 5 internal audits and any necessary action plans are reported and discussed with the RC-MDT, with documentation in the RC-MDT meeting minutes
- The RCP Director attends at least one of the NAPRC facility's CoC committee meetings, and reports the results of all required Chapter 5 internal audits, with documentation in the CoC committee meeting minutes

2.3 Rectal Cancer Program Coordinator

Definition and Requirements

The RCP Coordinator provides comprehensive administrative support to Rectal Cancer Multidisciplinary Team (RC-MDT) meetings, including the management of accurate and timely information to enable clinical decision making at the RC-MDT meeting. The RCP Coordinator must be a member of the RC-MDT. The RCP Coordinator is responsible for registering and monitoring patients with suspected and confirmed rectal cancer throughout their diagnostic and treatment pathways. The RCP Coordinator oversees adherence to patient care pathways, following RC-MDT guidelines, including time targets for relevant interventions. A Co-Coordinator may be appointed at the discretion of the NAPRC-accredited program.

The appointment of the RCP Coordinator or RCP Co-Coordinators must take place at least once during each accreditation cycle at the first meeting of any calendar year and must be documented in the RC-MDT meeting minutes. If Co-Coordinators are appointed, both must individually meet the RC-MDT meeting attendance requirements outlined in Standard 2.5. If the RCP Coordinator cannot continue to serve on the RC-MDT, a new, qualified RCP Coordinator must be appointed at the next RC-MDT meeting, and the appointment must be documented in the RC-MDT meeting minutes.

A protocol must be developed and implemented to outline patient management, including, but not limited to, communication between departments within the facility, referring physicians, and patients; coordinating patient appointments; and oversight of data collection. The RCP Coordinator must communicate with relevant departments within the facility to compile all pertinent information for RC-MDT meetings. Additionally, the RCP Coordinator is responsible for communication with referring organizations and providers to capture all relevant patient details for discussion during RC-MDT meetings.

The RCP Coordinator must proactively coordinate patient pathways with health care providers and organizations, and oversee booking for all appointments, diagnostic tests, and treatments within the time targets defined by the NAPRC standards. This is not exclusively a navigation position prioritizing interaction with patients. It is a behind-the-scenes position actively coordinating patient care with health care providers. It is recognized that the RCP Coordinator may need to contact the patient to obtain information about dates, locations, and results of tests and treatments performed outside of the NAPRC-accredited program.

Documentation

Submitted with Pre-Review Questionnaire

- RC-MDT meeting minutes
- Required protocol for outlining patient management

Measure of Compliance

The NAPRC-accredited program fulfills all compliance criteria:

- The RCP Coordinator is appointed at least once during each accreditation cycle at the first meeting of any calendar year, with documentation in the RC-MDT meeting minutes
- A protocol is developed and implemented to outline patient management, including coordination of appointments, communication between departments within the facility, communication with referring physicians and referring organizations, and oversight of patient data collection

2.4 Rectal Cancer Multidisciplinary Team Meetings

Definition and Requirements

Each calendar year, the Rectal Cancer Multidisciplinary Team (RC-MDT) must meet at least twice each calendar month. The RC-MDT may choose to meet more frequently to complete patient discussions and confirm treatment decisions in a timely manner.

A calendar year is defined as January 1–December 31. A calendar month is defined as the first day of the month through the last day of the month (for example, March 1 to March 31).

All RC-MDT meetings must be attended by at least one appointed RC-MDT member from each of the following specialties: surgery, pathology, radiology, medical oncology, and radiation oncology. This requirement must be met for all RC-MDT meetings, even if the RC-MDT meets more than twice each calendar month. If all five required specialties are not represented by at least one appointed RC-MDT member, the meeting does not meet the measure of compliance for this standard and cannot be counted towards the individual physician meeting attendance requirements outlined in Standard 2.5.

Attendance at RC-MDT meetings via videoconference and/ or teleconference is acceptable, but the virtual attendee(s) must have access to all meeting materials required for full participation and input, such as imaging studies, specimen photographs, and pathology reports and/or slides.

All RC-MDT meeting minutes must contain sufficient detail to accurately reflect the activities of the RC-MDT and demonstrate compliance with all applicable NAPRC standards requirements.

Documentation

Submitted with Pre-Review Questionnaire

- RC-MDT Attendance Template
- RC-MDT meeting minutes

Documentation uploaded into the Pre-Review Questionnaire must have all protected health information removed.

It is expected that programs follow local, state, and federal requirements related to patient privacy, risk management, and peer review for all standards of accreditation. These requirements vary state-to-state.

Measure of Compliance

Each calendar year, the NAPRC-accredited program fulfills all compliance criteria:

- The RC-MDT meets at least twice each calendar month
- Every meeting of the RC-MDT is attended by at least one appointed RC-MDT member from surgery, pathology, radiology, radiation oncology, and medical oncology, including all required meetings and any additional meetings

Bibliography

See Bibliography listed in Standard 2.1.

2.5 Rectal Cancer Multidisciplinary Team Attendance

Definition and Requirements

Each calendar year, individual members of the Rectal Cancer Multidisciplinary Team (RC-MDT) must meet the minimum RC-MDT meeting attendance requirements for their specialty or role as outlined in the table below:

Specialty/Role	Minimum RC-MDT Meeting Attendance Requirements
Rectal Cancer Program Director	50%
Rectal Cancer Program Coordinator	50%
Lead pathologist, radiologist, medical oncologist, and radiation oncologist	30%
Surgeons	50%
Pathologists	20%
Radiologists	20%
Radiation Oncologists	20%
Medical Oncologists	20%

Attendance at RC-MDT meetings via videoconference and/ or teleconference is acceptable, but the virtual attendee(s) must have access to all meeting materials required for full participation and input, such as imaging studies, specimen photographs, and pathology reports and/or slides. RC-MDT physician members involved in the evaluation and management of patients with rectal cancer at multiple NAPRC-accredited programs are only required to participate as a member of the RC-MDT at one of the NAPRC-accredited programs where they provide care. Such physicians must provide a letter of attestation documenting RC-MDT membership and at least the minimum required RC-MDT meeting attendance for their specialty and/or role at the facility of participation. The letter of attestation must be issued by the RC-MDT and the Rectal Cancer Program (RCP) Director at the facility of participation.

The RCP Director must monitor attendance each calendar year and address attendance outliers that do not meet the attendance requirements outlined in this standard.

Documentation

Submitted with Pre-Review Questionnaire

- RC-MDT Attendance Template
- RC-MDT meeting minutes

Documentation uploaded into the Pre-Review Questionnaire must have all protected health information removed.

It is expected that programs follow local, state, and federal requirements related to patient privacy, risk management, and peer review for all standards of accreditation. These requirements vary state-to-state.

Measure of Compliance

Each calendar year, the NAPRC-accredited program fulfills all compliance criteria:

- Each individual member of the RC-MDT meets the minimum attendance requirements for their specialty/role
- The RCP Director monitors attendance and addresses attendance outliers that do not meet the not meet the attendance requirements outlined in this standard



3

Facilities and Equipment Resources

Rationale

Commission on Cancer (CoC) accreditation requires the accredited cancer program to provide optimal resources for the care of patients with cancer. Accordingly, the rectal cancer program must be part of a CoC-accredited facility.

3.1 Commission on Cancer Accreditation

Definition and Requirements

The facility must be accredited by the Commission on Cancer (CoC) before earning accreditation by the National Accreditation Program for Rectal Cancer.

The CoC is a consortium of professional organizations dedicated to improving survival and quality of life for patients with cancer through standard setting, prevention, research, education, and the monitoring of comprehensive quality care. CoC accreditation is only granted to facilities that voluntarily commit to providing high-quality cancer care and compliance with established CoC standards.

High-quality rectal cancer care involves the same principles that underlie CoC accreditation. Accordingly, NAPRC accreditation is only granted to facilities that currently hold CoC accreditation status of Accredited or Accredited-Corrective Action Required.

Measure of Compliance

The NAPRC-accredited program fulfills all compliance criteria:

• The facility has a Commission on Cancer accreditation status of Accredited or Accredited-Corrective Action Required



4

Personnel and Services Resources

Rationale

Patients with cancer have a multitude of needs. NAPRCaccredited programs must oversee that patients receive appropriate care delivered by qualified professionals. The facility must maintain optimal resources for the care of patients with rectal cancer.

The responsibility is upon the cancer program to appropriately care for patients and develop criteria relative to the cancer program's available resources and experience.

Fulfilled by the Commission on Cancer standard requirements.


5

Patient Care: Expectations and Protocols

Rationale

Patient care expectations are the foundation of the National Accreditation Program for Rectal Cancer, including diagnostic workup, multidisciplinary presentation, and completeness of MRI, operative, and pathology reports.

These standards are intended solely as qualification criteria for NAPRC accreditation. They do not constitute a standard of care and are not intended to replace the medical judgment of the physician or health care professional in individual circumstances.

5.1 Local Excision of Rectal Cancer

Definition and Requirements

This standard addresses the management of high-risk malignant rectal lesions and any rectal cancer where advanced transanal procedures for local excision are performed. These procedures may include endoscopic mucosal resection (EMR), endoscopic submucosal dissection (ESD), transanal excision (TAE), or transanal endoscopic surgery (TES), including transanal endoscopy microsurgery (TEM), transanal minimally invasive surgery (TAMIS), and/or robotic transanal surgery (RTAS).

The NAPRC-accredited program must develop and implement a protocol to identify such cases for presentation and discussion by the RC-MDT. The criteria for identifying high-risk malignant rectal lesions that warrant presentation and discussion by the RC-MDT are established locally by the NAPRC-accredited program. The date of initial clinical evaluation is the date the case is first presented to the RC-MDT.

Cases of rectal cancer managed by the NAPRC-accredited program with a local excision procedure for definitive treatment are evaluated for compliance by the NAPRC using the **Requirements for Local Excision** outlined in each standard in Chapter 5 of *Optimal Resources for Rectal Cancer Care (2026 Standards)*.

The **Requirements for Local Excision** do **not** apply to cases where a local excision procedure is performed for diagnostic purposes with further definitive treatment recommended. Such cases must meet compliance with all applicable standards as written in Chapter 5.

Cases where the NAPRC-accredited program determines complete endoscopic removal of a lesion without any high-risk pathologic features are not within the scope of the NAPRC Standards and are not evaluated for compliance with any standard.

Cases managed with a local excision procedure without referral to the NAPRC-accredited program are not within the scope of the NAPRC Standards and are not evaluated for compliance with any standard.

Documentation

Submitted with Pre-Review Questionnaire

Required protocol

Documentation uploaded into the Pre-Review Questionnaire must have all protected health information removed.

It is expected that programs follow local, state, and federal requirements related to patient privacy, risk management, and peer review for all standards of accreditation. These requirements vary state-to-state.

Measure of Compliance

The NAPRC-accredited program fulfills all compliance criteria:

• A protocol is developed and implemented for identifying cases where a malignant rectal lesion is removed with a local excision procedure and must be presented and discussed by the RC-MDT

- 1. Shaukat A, Kaltenbach T, Dominitz JA et al. Endoscopic recognition and management strategies for malignant colorectal polyps: Recommendations of the US Multi-Society Task Force on Colorectal Cancer. *Gastroenterology* 2020;159:1916-34.
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- Tanaka S, Kashida H, Saito Y, et al. JGES guidelines for colorectal endoscopic submucosal dissection/endoscopic mucosal resection. *Dig Endosc* 2015;27(4):417-434.
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- Salinas HM, Dursun A, Klos CL, et al. Determining the need for radical surgery in patients with T1 rectal cancer. *Arch Surg* 2011;146(5):540-3.
- Kawaguti FS, Nahas CS, Marques CF, et al. Endoscopic submucosal dissection versus transanal endoscopic microsurgery for the treatment of early rectal cancer. *Surg Endosc.* 2014;28(4):1173-9.
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- 12. Bach SP, Hill J, Monson JRT, Transanal Endoscopic Microsurgery 1024 (TEM) Collaboration, et al. A predictive model for local recurrence after transanal endoscopic microsurgery for rectal cancer. *Br J Surg* 2009;96:280–90.
- 13. Dykstra MA, Gimen TI and Ronksley PE. Classic and novel histopathologic risk factors for lymph node metastasis in T1 colorectal cancer: A systematic review and meta-analysis. *Dis Colon Rectum* 2021;64:1139-1150.
- 14. Williams JG, Pullan RD, Hill J, et al. Management of the malignant colorectal polyp: ACPGBI position statement. *Colorectal Dis* 2013;15(Suppl 2):1–38.
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5.2 Review of Diagnostic Pathology

Definition and Requirements

Adenocarcinomas account for the vast majority of malignant tumors of the rectum in the United States. Other histologic types are rare, accounting for an estimated two to five percent (2–5%) of colorectal tumors. Every effort must be made to document the histopathological diagnosis of invasive adenocarcinoma of the rectum before the initiation of treatment. The NAPRC-accredited program must confirm the diagnosis of rectal cancer before the initiation of definitive treatment.

Patients with Rectal Cancer Previously Undiagnosed and Untreated

The NAPRC-accredited program must establish a protocol to confirm the diagnosis of rectal cancer prior to the initiation of definitive treatment.

A minimum of ninety percent (90%) of all previously undiagnosed and previously untreated patients with rectal cancer must have biopsy pathology confirming a diagnosis of rectal cancer before the initiation of definitive treatment at the NAPRC-accredited program.

Patients with Rectal Cancer Diagnosed Elsewhere

The NAPRC-accredited program must establish a protocol to obtain and review any outside biopsy pathology slides and/or biopsy pathology reports, whenever possible.

Before the initiation of definitive treatment at the NAPRCaccredited program:

- Outside biopsy pathology slides must be obtained and reviewed by a pathologist member of the RC-MDT
- If outside biopsy pathology slides cannot be obtained, outside biopsy pathology reports must be obtained and reviewed by a member of the RC-MDT
- If outside biopsy pathology slides or reports cannot be obtained for a patient without previous treatment, the NAPRC-accredited program must re-biopsy the patient
- If outside biopsy pathology slides or reports cannot be obtained for a patient with previous treatment, the NAPRC-accredited program must obtain medical documentation confirming a diagnosis of rectal cancer

The outside biopsy pathology slides and/or biopsy pathology reports must be reviewed by a member of the RC-MDT. Review of outside biopsy pathology slides and/or report by a member of the RC-MDT must be documented in the patient medical record. Confirmation of a diagnosis of rectal cancer must also be documented in the patient medical record.

Requirements for Local Excision

The NAPRC-accredited program must maintain compliance with this standard as written for malignant rectal lesions removed endoscopically or by local excision as definitive treatment.

Internal Medical Record Review

At a minimum, a random sample of twenty percent (20%) of eligible patient medical records, up to a maximum of 100 cases, must be reviewed by the RCP Director each calendar year to evaluate compliance with this standard. The RCP Director may delegate this review to an appropriately credentialed physician member of the RC-MDT. For any result that does not meet the required percentages as listed in the standard, an action plan must be developed and implemented.

Documentation

Reviewed During the Site Visit

• The site reviewer will evaluate pre-selected medical records to confirm compliance with the standard

Submitted with Pre-Review Questionnaire

- Protocol for confirming rectal cancer diagnosis with biopsy pathology in previously undiagnosed and previously untreated patients who receive definitive treatment at the NAPRC-accredited program
- Protocol to obtain and review outside biopsy pathology slides and/or reports for patients diagnosed elsewhere who receive definitive treatment at the NAPRC-accredited program

Documentation uploaded into the Pre-Review Questionnaire must have all protected health information removed.

It is expected that programs follow local, state, and federal requirements related to patient privacy, risk management, and peer review for all standards of accreditation. These requirements vary state-to-state.

Measure of Compliance

The NAPRC-accredited program fulfills all compliance criteria:

- Before initiation of definitive treatment by the NAPRCaccredited program, a minimum of ninety percent (90%) of previously undiagnosed and previously untreated patients with rectal cancer must have biopsy pathology confirming a diagnosis of rectal cancer
- Before the initiation of definitive treatment, patients with rectal cancer diagnosed elsewhere must have outside pathology slides and/or reports obtained and reviewed by a member of the RC-MDT to confirm a diagnosis of rectal cancer, with documentation in the patient medical record
- All required protocols are in place

- Kang H, O'Connell JB, Leonardi MJ, et al. Rare tumors of the colon and rectum: a national review. *Int J Colorectal Dis.* 2007;22(2):183-189.
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5.3 Systemic Staging with Computerized Tomography

Definition and Requirements

Thorough and accurate pre-treatment American Joint Committee on Cancer (AJCC) clinical staging of patients with rectal cancer forms the essential basis for the individualized treatment planning discussion that occurs at Rectal Cancer Multidisciplinary Team (RC-MDT) meetings. Clinical staging of rectal cancer has two components: "systemic staging" to diagnose distant metastatic disease (for example, liver and lung metastases) and "local tumor staging" to define the extent of the primary tumor in the rectum and involvement of regional pelvic lymph nodes (for example, mesorectal and iliac).

The requirements for systemic staging are discussed in this standard. The requirements for local staging are discussed in Standard 5.4.

Systemic staging for rectal cancer is completed by Computerized Tomography (CT) or Positron Emission Tomography-Computed Tomography (PET/CT) scan of the chest, abdomen, and pelvis. Systemic staging must be completed by CT whenever possible; however, a combined PET/CT scan is an acceptable alternative. A PET scan without the CT scan does not meet the measure of compliance for this standard.

A minimum of ninety percent (90%) of all previously untreated patients with rectal cancer must have completed systemic staging by CT or PET/CT scan of the chest, abdomen, and pelvis before definitive treatment is initiated by the NAPRC-accredited program. The CT or PET/CT scans must be presented and discussed by the RC-MDT.

Patients with documented contraindications to CT and/or PET/CT scans are exempt from this standard.

The CT of the pelvis may be omitted if there is anatomic structural continuity between the last slice of the abdominal CT and the first slice of the pelvic MRI. If the NAPRCaccredited program chooses to forego a CT of the pelvis, the continuation must be documented in a consistent manner (for example, it is always documented in the RC-MDT minutes, treatment recommendation summary, or MRI report). The method and location of consistent documentation of the reason for the absence of the CT of the pelvis must be included within the rectal cancer staging protocol.

Requirements for Local Excision

The NAPRC-accredited program must maintain compliance with this standard as written for malignant rectal lesions removed endoscopically or by local excision as definitive treatment.

When invasive rectal cancer is determined as a result of local excision, the NAPRC-accredited program must complete systemic staging by CT or PET/CT scan of the chest, abdomen, and pelvis within ninety (90) days of the date of the signed pathology report diagnosing rectal cancer.

Internal Medical Record Review

At a minimum, a random sample of twenty percent (20%) of eligible patient medical records, up to a maximum of 100 cases, must be reviewed by the Rectal Cancer Program (RCP) Director each calendar year to evaluate compliance with this standard. The RCP Director may delegate this review to an appropriately credentialed physician member of the RC-MDT. For any result that does not meet the required percentages as listed in this standard, a corrective action plan must be developed and implemented.

Documentation

Reviewed During the Site Visit

• The site reviewer will evaluate pre-selected medical records to confirm compliance with the standard

Submitted with Pre-Review Questionnaire

• Protocol for systemic staging of rectal cancer using CT or PET/CT exam of the chest, abdomen, and pelvis

Documentation uploaded into the Pre-Review Questionnaire must have all protected health information removed.

It is expected that programs follow local, state, and federal requirements related to patient privacy, risk management, and peer review for all standards of accreditation. These requirements vary state-to-state.

Measure of Compliance

The NAPRC-accredited program fulfills all compliance criteria:

- A minimum of ninety percent (90%) of previously untreated patients with rectal cancer have completed systemic staging by CT or PET/CT scan of the chest, abdomen, and pelvis before definitive treatment is initiated by the NAPRC-accredited program
- The CT or PET/CT must be presented and discussed by the RC-MDT
- All required protocols are in place

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- Horvat N, Carlos Tavares Rocha C, Clemente Oliveira B, Petkovska I, Gollub MJ. MRI of Rectal Cancer: Tumor Staging, Imaging Techniques, and Management. Radiographics. 2019 Mar-Apr;39(2):367-387. doi: 10.1148/ rg.2019180114. Epub 2019 Feb 15. PMID: 30768361; PMCID: PMC6438362.

5.4 Local Staging and Standardized Reporting with Magnetic Resonance Imaging

Definition and Requirements

Magnetic Resonance Imaging (MRI) has replaced endorectal ultrasound (EUS) as the primary imaging modality used for the local staging of rectal cancer. MRI's significant advantages over EUS include: the ability to have independent review, improved accuracy of extramural depth of invasion and extramural vascular invasion, detection of the anticipated circumferential margin clearance, and the ability to compare pre- and post-treatment studies.

A minimum of ninety percent (90%) of all newly diagnosed patients with rectal cancer must have completed local staging by MRI before definitive treatment is initiated by the NAPRCaccredited program. The MRI results must be presented and discussed by the RC-MDT.

The protocol for MRI staging of rectal cancer has been refined and standardized by European and American experts. For MRI staging to be effective, the technique of acquiring and interpreting the images must be uniform and the results must be reported in a standardized report. Without standardized reporting, less than forty percent (40%) of MRI reports contain all of the necessary information to make treatment decisions.

All MRI results, including initial and post-treatment MRI results, must be read by a radiologist member of the RC-MDT. The MRI staging results must be recorded in a standardized synoptic report containing the minimum required elements defined by the Society of Abdominal Radiology (SAR). These requirements are available on the SAR website. The standardized synoptic report must be included in the patient medical record.

For patients with documented contraindications to MRI scans, local staging by endorectal ultrasound (EUS) must be completed before definitive treatment is initiated by the NAPRC-accredited program.

Requirements for Local Excision

A minimum of ninety percent (90%) of malignant rectal lesions managed with local excision procedures must have completed local staging by MRI before definitive treatment is initiated by the NAPRC-accredited program. When invasive rectal cancer is determined as a result of local excision, the NAPRC-accredited program must complete local staging by MRI within ninety (90) days of the date of the signed pathology report diagnosing rectal cancer.

The MRI results must be read by a radiologist member of the RC-MDT. The MRI results must be presented and discussed by the RC-MDT. The MRI results must be recorded in a standardized synoptic report containing the minimum required elements. The required elements are defined in the <u>Appendix</u> of *Optimal Resources for Rectal Cancer Care* (2026 Standards). The standardized synoptic report must be included in the patient medical record.

Internal Medical Record Review

At a minimum, a random sample of twenty percent (20%) of eligible patient medical records, up to a maximum of 100 cases, must be reviewed by the Rectal Cancer Program (RCP) Director each calendar year to evaluate compliance with this standard. The RCP Director may delegate this review to an appropriately credentialed physician member of the RC-MDT. For any result that does not meet the required percentages as listed in the standard an action plan must be developed and implemented.

Documentation

Reviewed During the Site Visit

• The site reviewer will evaluate pre-selected medical records to confirm compliance with the standard

Submitted with Pre-Review Questionnaire

- Protocol for local tumor staging of rectal cancer using MRI of the pelvis
- Example template for standardized synoptic reporting of MRI staging results

Documentation uploaded into the Pre-Review Questionnaire must have all protected health information removed.

It is expected that programs follow local, state, and federal requirements related to patient privacy, risk management, and peer review for all standards of accreditation. These requirements vary state-to-state.

Measure of Compliance

The NAPRC-accredited program fulfills all compliance criteria:

- A minimum of ninety percent (90%) of all newly diagnosed patients with rectal cancer must have completed local staging by MRI before definitive treatment is initiated by the NAPRC-accredited program
- The MRI results must be presented and discussed by the RC-MDT
- A minimum of ninety percent (90%) of MRI staging results for patients with rectal cancer are reported in standardized synoptic format containing all required elements, and are included in the patient medical record
- The MRI results are read by a radiologist member of the RC-MDT

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5.5 Carcinoembryonic Antigen Level

Definition and Requirements

Testing for Carcinoembryonic Antigen (CEA) Level, a glycoprotein that is released from tumor cells into patient serum, is recommended by the National Comprehensive Cancer Network (NCCN) guidelines for both colon and rectal cancer. Testing must be completed before initiation of treatment in patients with rectal cancer. CEA levels are also useful as a baseline for surveillance after treatment.

A protocol must be in place for obtaining and tracking pretreatment CEA levels for all previously untreated patients with rectal cancer.

A minimum of seventy-five percent (75%) of all previously untreated patients with rectal cancer must have a CEA level test completed before definitive treatment is initiated by the NAPRC-accredited program.

The pre-treatment CEA level is not required for the patient presentation and discussion at the RC-MDT meeting, but once it is available, it must be documented in the patient medical record and the treatment recommendation summary or the treatment outcome summary.

Requirements for Local Excision

The NAPRC-accredited program must maintain compliance with this standard as written for malignant rectal lesions removed endoscopically or by local excision as definitive treatment.

Internal Medical Record Review

At a minimum, a random sample of twenty percent (20%) of eligible patient medical records, up to a maximum of 100 cases, must be reviewed by the Rectal Cancer Program (RCP) Director each calendar year to evaluate compliance with this standard. The RCP Director may delegate this review to an appropriately credentialed physician member of the Rectal Cancer Multidisciplinary Team. For any result that does not meet the required percentages as listed in the standard, an action plan must be developed and implemented.

Documentation

Reviewed During the Site Visit

• The site reviewer will evaluate pre-selected medical records to confirm compliance with the standard

Submitted with Pre-Review Questionnaire

• Protocol for obtaining and tracking pre-treatment CEA levels for all previously untreated patients with rectal cancer

Documentation uploaded into the Pre-Review Questionnaire must have all protected health information removed.

It is expected that programs follow local, state, and federal requirements related to patient privacy, risk management, and peer review for all standards of accreditation. These requirements vary state-to-state.

Measure of Compliance

The NAPRC-accredited program fulfills all compliance criteria:

- A minimum of seventy-five percent (75%) of previously untreated patients with rectal cancer have a CEA level test before definitive treatment is initiated. The results are documented in the patient medical record
- All required protocols are in place

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5.6 Treatment Planning Discussion and Recommendation Summary

Definition and Requirements

Compliance with this standard is evaluated based on the completion of the required Rectal Cancer Multidisciplinary Team (RC-MDT) treatment planning discussion and the treatment recommendation summary. Compliance with required diagnostic and staging studies is evaluated in Standards 5.2 – 5.5.

Treatment Planning Discussion

A minimum of ninety percent (90%) of patients with rectal cancer who undergo treatment at a NAPRC-accredited program, excluding emergency patients, must be presented and discussed by the RC-MDT before the initiation of treatment. Treatment is defined as neoadjuvant therapy, surgical resection, local excision, or initiation of palliative care. The treatment planning discussion requirements for local excision procedures are outlined separately.

Emergency patients who do not require a treatment planning discussion are those that present with tumor-related complications that require immediate or urgent intervention. Examples of emergent conditions include, but are not limited to, the following: rectal tumor perforation, life-threatening tumor hemorrhage, and acute large bowel obstruction. Documentation of immediate or urgent intervention must be included in the patient medical record.

The RC-MDT treatment planning discussion must include, but is not limited to, the following topics:

1. Review of diagnostic and staging studies

- Colonoscopy report, including primary tumor location
 and synchronous lesions
- Biopsies of primary rectal cancer and metastases (Standard 5.2)
- CT scan or PET/CT of chest, abdomen, and pelvis (Standard 5.3)
- MRI of the pelvis (Standard 5.4)
- Pre-treatment Carcinoembryonic Antigen Level, if available (Standard 5.5)
- 2. Assignment of clinical stage
 - Clinical stage according to the American Joint Committee on Cancer (AJCC)

- 3. Creation of individualized treatment plan
 - Watch and wait surveillance, when indicated
 - Neoadjuvant therapy, when indicated
 - Surgical procedure, when indicated
 - Referral to radiation oncology, when indicated
 - Referral to medical oncology, when indicated
 - Palliative care, when indicated

The NAPRC-accredited program must consult with its legal and/or risk management department(s) to conform to local requirements for conducting and documenting multidisciplinary team treatment planning discussions and communicating with the patient.

For NAPRC-accredited programs with 100 or more cases in a calendar year, the RCP Director may develop criteria to determine which cases must be presented and discussed by the RC-MDT for a treatment planning discussion. These criteria must be documented in a protocol. Regardless of criteria put in place, at least 100 cases must be presented for treatment planning discussion each calendar year in accordance with the requirements outlined in this standard. Cases that are not presented and discussed by the RC-MDT must still meet the requirements outlined in all other applicable standards.

Treatment Planning Discussion for Local Excision

A minimum of ninety percent (90%) of patients with rectal lesions managed by diagnostic or definitive treatment local excision must be presented and discussed by the RC-MDT for a treatment planning discussion. If the NAPRC-accredited program determines complete endoscopic removal of a lesion without any high-risk pathologic features the case does not have to be presented to the RC-MDT. The determination of local excision as diagnostic or definitive treatment is be made by the NAPRC-accredited program. In some cases, diagnostic local excision may be determined to be definitive treatment during the treatment planning discussion. The RC-MDT treatment planning discussion for local excision must include the following:

- 1. Review of initial colonoscopy and/or transanal resection operative report
 - Statement of the local excision(s) as being diagnostic, or definitive treatment
 - Lesion marking performed (ink tattoo, clips), or accurately localized by proctoscopy
 - Lesion orientation (anterior, posterior, left, right), size, and morphology (polypoid, pedunculated, sessile)
 - Measurement from anal verge or the dentate line to distal margin of original lesion
 - Local excision technique and depth of excision
 - Review of subsequent endoscopic/operative report(s) of local re-excision of polypectomy scar/residual lesion, if applicable
 - Review of pathology slides of the initial local excision (Standard 5.2)
 - Assessment of sphincter involvement (yes/no), if possible
- 2. Review of staging studies
 - CT scan or PET/CT of chest, abdomen, and pelvis (Standard 5.3)
 - MRI of the pelvis (Standard 5.4)
 - CEA level (Standard 5.5)
 - EUS report, if performed
- 3. Consideration of patient factors and preferences
 - Examples of considerations for discussion may include the following, as indicated:
 - Discussion of risks and benefits of local excision vs radical resection, as part of the shared decisionmaking process
 - Patient functional status and major comorbidities
 - Anticipated non-compliance or barriers that may inhibit compliance with the recommended surveillance protocol
 - Patient preference for organ preservation, or avoidance of long-term dysfunction after surgery
 - Patient preference to avoid neoadjuvant or adjuvant therapy
- 4. Creation of an individualized treatment plan
 - Watch and wait surveillance, when indicated
 - Local excision, when indicated
 - Neoadjuvant or adjuvant treatment, when indicated
 - Radical surgery, when indicated
 - Palliative care, when indicated

Treatment Recommendation Summary

A treatment recommendation summary must be provided to the treating physician for a minimum of fifty percent (50%) of patients with rectal cancer.

The treatment recommendation summary requirements outlined below are applicable for all patients presented and discussed by the RC-MDT, including those managed by definitive treatment local excision. If the treatment planning discussion determines a diagnostic local excision to be the definitive treatment, both the treatment recommendation summary and the treatment outcome summary may be completed during the same RC-MDT meeting. The requirements for the treatment outcome summary are outlined in Standard 5.11. The treatment recommendation summary and the treatment outcome summary must meet all requirements as outlined in Standard 5.6 and Standard 5.11, respectively.

A treating physician is defined as the provider of record treating the patient's rectal cancer who seeks the opinion of the RC-MDT. The treating physician is responsible for ensuring communication of treatment recommendations to the patient.

If the treating physician is in attendance for the RC-MDT presentation and discussion of their patient, a treatment recommendation summary does not need to be provided to them to meet the measure of compliance for this standard.

The treatment recommendation summary must include, but is not limited to, the following:

- Tumor location in the rectum (lower, middle, or upper third)
- Specification of any sphincter involvement
- Clinical (pre-treatment) American Joint Committee on Cancer (AJCC) stage
- Pre-treatment circumferential resection margin status (not threatened, threatened, or involved)
- Carcinoembryonic Antigen Level, if available
- Neoadjuvant therapy recommendation
- Type and duration of neoadjuvant therapy recommended
- Anticipated date and type of surgical procedure
- Clinical research study eligibility and/or enrollment
- Microsatellite instability status

Internal Medical Record Review

At a minimum, a random sample of twenty percent (20%) of eligible patient medical records, up to a maximum of 100 cases, must be reviewed by the RCP Director each calendar year to evaluate compliance with this standard. The RCP Director may delegate this review to an appropriately credentialed physician member of the RC-MDT. For any result that does not meet the required percentages as listed in the standard, an action plan must be developed and implemented.

Documentation

Reviewed During the Site Visit

• The site reviewer will evaluate pre-selected medical records to confirm compliance with the standard

Submitted with Pre-Review Questionnaire

- Protocol for treatment planning discussion of patients with rectal cancer at a RC-MDT meeting
- Protocol for completing the treatment recommendation summary and providing it to the treating physician
- Template for the standardized evaluation and treatment recommendation summary
- For NAPRC-accredited programs with more than 100 patients per year, a protocol outlining criteria used to determine which patients are discussed by the RC-MDT for treatment planning

Documentation uploaded into the Pre-Review Questionnaire must have all protected health information removed.

It is expected that programs follow local, state, and federal requirements related to patient privacy, risk management, and peer review for all standards of accreditation. These requirements vary state-to-state.

Measure of Compliance

The NAPRC-accredited program fulfills all compliance criteria:

- Excluding emergency patients, an individualized treatment planning discussion is conducted at a RC-MDT meeting for a minimum of ninety percent (90%) of patients with rectal cancer before initiation of definitive treatment
- A treatment recommendation summary is completed and provided to the patient's treating physician for a minimum of fifty percent (50%) of patients with rectal cancer before initiation of definitive treatment
- All required protocols are in place

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- Karagkounis G, Stocchi L, Lavery IC, Liska D, Gorgun E, Veniero J, Plesec T, Amarnath S, Khorana AA, Kalady MF. Multidisciplinary conference and clinical management of rectal Cancer. J Am Coll Surg. 2018;226:874–880.

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5.7 Definitive Treatment Timing

Definition and Requirements

Once a diagnosis of rectal cancer has been made, the NAPRCaccredited program is responsible for patients receiving a thorough and efficient evaluation for prompt initiation of therapy. A patient-centered approach dictates minimal delay between diagnosis and treatment to avoid undue patient anxiety.

A minimum of eighty percent (80%) of previously untreated patients must begin definitive treatment within sixty (60) days of the patient's initial clinical evaluation for rectal cancer at the NAPRC-accredited program. The treatment plan must be documented in the patient medical record.

The date of initial clinical evaluation is the date of the signed pathology report diagnosing rectal cancer. For patients presenting to the NAPRC-accredited program with a previous diagnosis of rectal cancer, the date of initial clinical evaluation is the date the patient presents to the NAPRC-accredited program for treatment or further management of the rectal cancer.

Compliance with this standard is not affected by documented treatment delays resulting from patient inaction or delayed payer authorization for recommended treatment.

Requirements for Local Excision

When invasive rectal cancer is determined prior to local excision and local excision is initiated as definitive treatment, the NAPRC-accredited program must maintain compliance with this standard as outlined above. The determination of local excision as definitive treatment must be made by the RC-MDT.

When invasive rectal cancer is determined as a result of local excision and no further treatment is recommended, this standard is not applicable as definitive treatment has been completed at the time of diagnosis.

When invasive rectal cancer is determined at the time of local excision and further definitive treatment is recommended, the patient must begin definitive treatment within sixty (60) days of the RC-MDT treatment planning discussion.

Internal Medical Record Review

At a minimum, a random sample of twenty percent (20%) of eligible patient medical records, up to a maximum of 100 cases, must be reviewed by the RCP Director each calendar year to evaluate compliance with this standard. The RCP Director may delegate this review to an appropriately credentialed physician member of the RC-MDT. For any result that does not meet the required percentages as listed in the standard, an action plan must be developed and implemented.

Documentation

Reviewed During the Site Visit

• The site reviewer will evaluate pre-selected medical records to confirm compliance with the standard.

Documentation uploaded into the Pre-Review Questionnaire must have all protected health information removed.

It is expected that programs follow local, state, and federal requirements related to patient privacy, risk management, and peer review for all standards of accreditation. These requirements vary state-to-state.

Measure of Compliance

The NAPRC-accredited program fulfills all compliance criteria:

• A minimum of eighty percent (80%) of previously untreated patients with rectal cancer begin definitive treatment within sixty (60) days of the patient's initial clinical evaluation for rectal cancer at the NAPRCaccredited program

- Korsgaard M, Pedersen L, Sørensen H T, Laurberg S. Delay of treatment is associated with advanced stage of rectal cancer but not of colon cancer. *Cancer Detection and Prevention.* 2006;30(4):341-346.
- Iversen LH, Antonsen S, Laurberg S, Lautrup MD. Therapeutic delay reduces survival of rectal cancer but not of colonic cancer. *Br J Surg.* 2009;96(10):1183-1189.
- 3. Ramos M, Esteva M, Cabeza E, Campillo C, Llobera J, Aguilo A. Relationship of diagnostic and therapeutic delay with survival in colorectal cancer: A review. *European J of Cancer*. 2007;43(17):2467-2478.
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5.8 Surgical Resection and Standardized Operative Reporting

Definition and Requirements

Surgery Standardization

Surgeon specialization has been shown to improve rectal cancer outcomes. Proper surgical technique is vital to optimizing oncological outcomes and minimizing morbidity in rectal cancer surgery. The operative technique of total mesorectal excision (TME) is technically demanding and a clear correlation exists between surgeon experience and knowledge and patient outcomes, which may partially explain observed discrepancies between high- and low-volume surgeons. To encourage standardization and adherence to standards, rectal cancer surgery must be performed by a member of the Rectal Cancer Multidisciplinary Team (RC-MDT).

A minimum of eighty percent (80%) of all surgical resections for patients with rectal cancer must be performed by a surgeon who is an appointed member of the RC-MDT.

Standardized Synoptic Reporting

The use of checklists for complex processes is widely advocated in many fields, including medicine, where particular attention has been paid toward procedural-based specialties like surgery. Checklist implementation is credited with significant reductions in rates of inpatient complications and perioperative mortality in both developing and mature health care systems.

The use of synoptic operative reporting in rectal cancer has been shown to increase the completeness and reliability of documentation of critical elements when compared to narrative reporting.

Operative reports for a minimum of ninety percent (90%) of all patients with rectal cancer who undergo surgical resection at the NAPRC-accredited program must be recorded in a standardized synoptic report containing the minimum required elements. The required elements are defined in the <u>Appendix</u> of *Optimal Resources for Rectal Cancer Care (2026 Standards)*.

Requirements for Local Excision

The NAPRC-accredited program must capture the minimum required elements in synoptic format for malignant rectal lesions removed endoscopically or by transanal excision. The required elements are defined in the <u>Appendix</u> of Optimal Resources for Rectal Cancer Care (2026 Standards).

Internal Medical Record Review

At a minimum, a random sample of twenty percent (20%) of eligible patient medical records, up to a maximum of 100 cases, must be reviewed by the RCP Director each calendar year to evaluate compliance with this standard. The RCP Director may delegate this review to an appropriately credentialed physician member of the RC-MDT. For any result that does not meet the required percentages as listed in the standard, an action plan must be developed and implemented.

Documentation

Reviewed During the Site Visit

• The site reviewer will evaluate pre-selected medical records to confirm compliance with the standard

Submitted with Pre-Review Questionnaire

• Example template for standardized synoptic reporting of operative reports

Documentation uploaded into the Pre-Review Questionnaire must have all protected health information removed.

It is expected that programs follow local, state, and federal requirements related to patient privacy, risk management, and peer review for all standards of accreditation. These requirements vary state-to-state.

Measure of Compliance

The NAPRC-accredited program fulfills all compliance criteria:

- Rectal cancer surgery is performed by a surgeon member of the RC-MDT for a minimum of eighty percent (80%) of patients undergoing surgical resection for rectal cancer at the NAPRC-accredited program
- Operative reports for a minimum of ninety percent (90%) of surgical resections and/or local excisions for rectal cancer are reported in standardized synoptic format containing all required elements and are included in the patient medical record

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- Maurer CA, Renzulli P, Kull C, Käser SA, Mazzucchelli L, Ulrich A, Büchler MW. The impact of the introduction of total mesorectal excision on local recurrence rate and survival in rectal cancer: Long-term results. *Ann Surg Oncol.* 2011;18(7):1899-1906.
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- Richardson DP, Porter GA, Johnson PM. Surgeon knowledge contributes to the relationship between surgeon volume and patient outcomes in rectal cancer. *Ann Surg.* 2013;257(2):295-301.

- Haynes AB, Weiser TG, Berry WR, et al, Safe Surgery Saves Lives Study Group. A surgical safety checklist to reduce morbidity and mortality in a global population. *N Engl J Med.* 2009;360:491-499.
- de Vries EN, Prins HA, Crolla RM, et al, SURPASS Collaborative Group. Effect of a comprehensive surgical safety system on patient outcomes. *N Engl J Med.* 2010;363:1928-1937.
- 12. Gawande A. The Checklist Manifesto: How to Get Things Right. New York, NY. Metropolitan Books. 2009.
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- 14. Glasgow SC, Morris AM, Baxter NN, Fleshman JW, Alavi KS, Luchtefeld MA, Monson JR, Chang GJ, Temple LK. Development of the American Society of Colon and Rectal Surgeons' rectal cancer surgery checklist. *Dis Colon Rectum.* 2016;59(7):601-606.
- 15. Maniar RL, Sytnik P, Wirtzfeld DA, Hochman DJ, McKay AM, Yip B, Hebbard PC, Park J. Synoptic operative reports enhance documentation of best practices for rectal cancer. *J Surg Oncol.* 2015;112(5): 555-560.
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- G A Porter, C L Soskolne, W W Yakimets, S C Newman. Surgeon-related factors and outcome in rectal cancer. Ann Surg. 1998 Feb; 227(2):157-67.
- 18. Heather L Yeo, Jonathan S Abelson, Jialin Mao, Paul R A O'Mahoney, Jeffrey W Milsom, Art Sedrakyan. Surgeon Annual and Cumulative Volumes Predict Early Postoperative Outcomes after Rectal Cancer Resection. Ann Surg. 2017 Jan; 265(1):151-157.
- Christopher T Aquina, Christian P Probst, Adan Z Becerra, James C Iannuzzi, Kristin N Kelly, Bradley J Hensley, Aaron S Rickles, Katia Noyes, Fergal J Fleming, John R T Monson. High volume improves outcomes: The argument for centralization of rectal cancer surgery. Surgery. 2016 Mar; 159(3):736-48.
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5.9 Pathology Reports after Surgical Resection

Definition and Requirements

Beyond the important staging characteristics of tumor depth of invasion (T-category) and nodal status (N-category), important diagnostic and prognostic information can be gained from an evaluation of the completeness of the mesorectal excision, the status of the circumferential margin, and the response of the tumor to neoadjuvant therapy (Tumor Regression Grade/Treatment Effect Score).

Pathologic assessment of the resected rectal cancer specimen provides critical information for prognosis, forms the basis for decisions on adjuvant therapy, serves as an important indicator of quality of surgery, and can validate the soundness of the Rectal Cancer Multidisciplinary Team (RC-MDT) discussion process.

A minimum of ninety percent (90%) of definitive rectal cancer surgical resection specimens of the primary tumor are read, and the pathology report completed, by a pathologist member of the RC-MDT. The pathology report must be completed within two weeks of the definitive surgical resection.

It is expected that pathology reports completed by the NAPRC-accredited program include all required data elements as outlined in the College of American Pathologists (CAP) Protocol for the Examination of Resection Specimens from Patients with Primary Carcinoma of the Colon and Rectum and use a standardized synoptic format.

Requirements for Local Excision

The NAPRC-accredited program must maintain compliance with this standard as written for malignant rectal lesions removed endoscopically or by local excision as definitive treatment.

The synoptic pathology report for local excision must include all of the elements in the CAP Protocol for the Examination of Excisional Biopsy or Polypectomy Specimens from Patients with Primary Carcinoma of the Colon and Rectum.

Internal Medical Record Review

At a minimum, a random sample of twenty percent (20%) of eligible patient medical records, up to a maximum of 100 cases, must be reviewed by the RCP Director each calendar year to evaluate compliance with this standard. The RCP Director may delegate this review to an appropriately credentialed physician member of the RC-MDT. For any result that does not meet the required percentages as listed in the standard, an action plan must be developed and implemented.

Documentation

Reviewed During the Site Visit

• The site reviewer will evaluate pre-selected medical records to confirm compliance with the standard

Submitted with Pre-Review Questionnaire

• Example template for standardized synoptic reporting of pathology specimens

Documentation uploaded into the Pre-Review Questionnaire must have all protected health information removed.

It is expected that programs follow local, state, and federal requirements related to patient privacy, risk management, and peer review for all standards of accreditation. These requirements vary state-to-state.

Measure of Compliance

The NAPRC-accredited program fulfills all compliance criteria:

• A minimum of ninety percent (90%) of definitive rectal cancer specimens of the primary tumor performed at the NAPRC-accredited program are read and the pathology report completed by a pathologist member of the RC-MDT within two weeks of the definitive surgical resection and/or local excision

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5.10 Specimen Photographs

Definition and Requirements

The integrity of the mesorectum correlates with oncologic outcomes. The plane in which the surgeon performs the dissection of the rectum will influence the completeness of the mesorectum and therefore reflects the quality of the surgery. The presence of mesorectal tears or defects predisposes to both local and distant recurrence. Photographs of the specimens displaying the integrity of the mesorectum provide useful feedback to the surgeon.

A minimum of sixty-five percent (65%) of rectal cancer specimens must be photographed to document the quality of the mesorectum and include anterior, posterior, and right and left lateral views. Photographs of the fresh or formalin fixed ex-vivo specimen may be obtained using any standard digital camera in either the operating room or in the pathology laboratory. The images must be labelled as to orientation. These images must be presented and discussed at Rectal Cancer Multidisciplinary Team (RC-MDT) meetings and must be electronically stored with a patient identifier.

If the specimen is photographed but not presented and discussed at an RC-MDT meeting, it cannot count towards the sixty-five percent (65%) minimum requirement for the measure of compliance for this standard.

Requirements for Local Excision

A minimum of sixty-five percent (65%) of rectal cancer specimens must be photographed to document the quality of the local excision. At least one (1) full-on view photograph of the specimen is required to meet compliance with this standard.

Internal Medical Record Review

At a minimum, a random sample of twenty percent (20%) of eligible patient medical records, up to a maximum of 100 cases, must be reviewed by the RCP Director each calendar year to evaluate compliance with this standard. The RCP Director may delegate this review to an appropriately credentialed physician member of the RC-MDT. For any result that does not meet the required percentages as listed in the standard, an action plan must be developed and implemented.

Documentation

Reviewed During the Site Visit

• The site reviewer will evaluate pre-selected medical records to confirm compliance with the standard

Submitted with Pre-Review Questionnaire

• Protocol for obtaining, displaying, and storing photographs of rectal cancer specimens

Documentation uploaded into the Pre-Review Questionnaire must have all protected health information removed.

It is expected that programs follow local, state, and federal requirements related to patient privacy, risk management, and peer review for all standards of accreditation. These requirements vary state-to-state.

Measure of Compliance

The NAPRC-accredited program fulfills all compliance criteria:

- A minimum of sixty-five percent (65%) of all eligible surgical specimens are photographed to include labelled anterior, posterior, and two lateral views and are presented and discussed by the RC-MDT
- A minimum of sixty-five percent (65%) of all eligible local excision specimens are photographed with at least one (1) full-on view and are presented and discussed by the RC-MDT
- All required protocols are in place

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5.11 Treatment Outcome Discussion and Outcome Summary

Definition and Requirements

Compliance with this standard is evaluated based on the completion of the required Rectal Cancer Multidisciplinary Team (RC-MDT) treatment outcome discussion and the treatment outcome summary. Compliance with standardized operative reporting, final pathology reporting, and specimen photography is evaluated in Standards 5.8 – 5.10.

Treatment Outcome Discussion

A minimum of ninety percent (90%) of patients with rectal cancer who receive treatment (including total neoadjuvant therapy, neoadjuvant therapy, surgical resection, local excision, and patients under consideration for watch and wait surveillance) at the NAPRC-accredited program must be presented and discussed by the RC-MDT for a treatment outcome discussion. The treatment outcome discussion must occur within four weeks of completion of the patient's workup and treatment. For total neoadjuvant therapy, the treatment outcome discussion must occur within 150 days of completion of the patient's treatment.

The treatment outcome discussion for patients with rectal cancer must include, but is not limited to, the following elements, as applicable based on treatment modality:

Neoadjuvant Therapy

1. Evaluation

- Pre-treatment clinical stage according to American Joint Committee on Cancer (AJCC)
- Pre-treatment Carcinoembryonic Antigen Level
- 2. Treatment
 - Type of neoadjuvant therapy
 - Date of completion for neoadjuvant therapy
 - Post-treatment MRI to evaluate clinical response
 - · Post-treatment endoscopy to evaluate clinical response
 - Final clinical stage or post-therapy y-pathological stage according to the AJCC
 - Recommendation for watch and wait surveillance, surgical resection, further chemoradiation, or palliative care

Local Excision

- 1. Pre-excision Evaluation and Treatment
 - Clinical stage according to American Joint Committee on Cancer (AJCC)
 - Neoadjuvant therapy
- 2. Review of Excisional Outcome
 - Modality (conventional transanal excision, EMR, ESD, TAE, TES, TEM, TAMIS, RTAS)
 - Unexpected findings
 - Specimen photograph(s)
 - Post-excisional complications that may impact further treatment
- 3. Review of Final Pathology Report and Stage
 - College of American Pathologists (CAP) local excision synoptic pathology report
 - Tumor Regression Grade/Treatment Effect Score, if applicable
 - Pathological stage or post-therapy y-pathological stage according to the AJCC
- 4. Recommendations for Surveillance by the RC-MDT
 - Carcinoembryonic Antigen Level
 - MRI
 - CT/PET scan
 - Endoscopy

Surgical Resection

- 1. Presurgical Evaluation and Treatment
 - Clinical stage according to American Joint Committee on Cancer (AJCC)
 - Neoadjuvant therapy
 - Pre-treatment Carcinoembryonic Antigen Level
- 2. Review of Surgical Outcome
 - Modality (open, laparoscopic, robotic)
 - Creation of stoma and type of stoma (if applicable)
 - Unexpected findings (for example, metastatic disease, adjacent organ involvement, grossly involved margins after resection)
 - Specimen photographs
 - Postoperative complications that may impact further treatment
- 3. Review of Final Pathology Report and Stage
 - Circumferential Resection Margin and Distal Margin Status (either mm or cm may be used)
 - Tumor Regression Grade/Treatment Effect Score
 - Mesorectal Grade
 - Pathological stage or post-therapy y-pathological stage according to the AJCC

- 4. Recommendation for Adjuvant Therapy
 - Adjuvant therapy regimen, when indicated
 - Referral to medical oncology, when indicated
 - Referral to radiation oncology, when indicated
 - Palliative care, when indicated

For NAPRC-accredited programs with 100 or more cases in a calendar year, the RCP Director may develop criteria to determine which cases must be presented and discussed by the RC-MDT for a treatment outcome discussion. These criteria must be documented in a protocol. Regardless of criteria put in place, at least 100 cases must be presented for treatment outcome discussion each calendar year, in accordance with the requirements outlined in this standard. Cases that are not presented and discussed by the RC-MDT must still meet the requirements outlined in all other applicable standards.

Treatment Outcome Summary

A standardized treatment outcome summary provides documentation of the treatment provided for the patient's rectal cancer and prognostic information based on tumor staging and other pathological factors.

The treatment outcome summary must be provided to the treating physician for a minimum of fifty percent (50%) of patients within four weeks of the treatment outcome discussion.

The treatment outcome summary must include, but is not limited to, the following information:

- Pre-treatment clinical stage according to American Joint Committee on Cancer (AJCC)
- Pre-treatment Carcinoembryonic Antigen Level
- Neoadjuvant therapy
- Type and duration of neoadjuvant therapy, and date of completion
- Local excision procedure and date of procedure, if applicable
- Surgical procedure and date of procedure, if applicable
- Final pathological stage or post-therapy y-pathological stage according to AJCC
- Tumor Regression Grade/Treatment Effect Score
- Microsatellite instability status
- Circumferential Resection Margin
- Distal Resection Margin
- Mesorectal Grade
- Recommendation for adjuvant therapy and, if applicable, adjuvant therapy regimen

Requirements for Local Excision

The NAPRC-accredited program must maintain compliance with this standard as written for malignant rectal lesions removed endoscopically or by local excision as definitive treatment.

If the treatment planning discussion determines a diagnostic local excision to be the definitive treatment, both the treatment recommendation summary and the treatment outcome summary may be completed during the same RC-MDT meeting. The requirements for the treatment recommendation summary are outlined in Standard 5.6. The treatment recommendation summary and the treatment outcome summary must meet all requirements as outlined in Standard 5.6 and Standard 5.11, respectively.

Internal Medical Record Review

At a minimum, a random sample of twenty percent (20%) of eligible patient medical records, up to a maximum of 100 cases, must be reviewed by the RCP Director each calendar year to evaluate compliance with this standard. The RCP Director may delegate this review to an appropriately credentialed physician member of the RC-MDT. For any result that does not meet the required percentages as listed in the standard, an action plan must be developed and implemented.

Documentation

Reviewed During the Site Visit

• The site reviewer will evaluate pre-selected medical records to confirm compliance with the standard

Submitted with Pre-Review Questionnaire

- Protocol used to monitor treatment completion status for each patient with rectal cancer and scheduling for patient presentation at an RC-MDT meeting following completion of treatment
- For NAPRC-accredited programs with more than 100 patients with rectal cancer in a calendar year, protocol detailing criteria used to determine which patients are discussed at the RC-MDT for a treatment outcome discussion
- A template for the standardized content of the treatment outcome summary
- Protocol to generate and disseminate treatment outcome summaries to patients' treating physician(s)

Documentation uploaded into the Pre-Review Questionnaire must have all protected health information removed.

It is expected that programs follow local, state, and federal requirements related to patient privacy, risk management, and peer review for all standards of accreditation. These requirements vary state-to-state.

Measure of Compliance

The NAPRC-accredited program fulfills all compliance criteria:

- A minimum of ninety percent (90%) of patients with rectal cancer who receive treatment at the NAPRC-accredited program are presented and discussed by the RC-MDT for a treatment outcome discussion within four weeks of completion of treatment, or within 150 days of treatment for total neoadjuvant therapy
- The treatment outcome summary is provided to the treating physician for a minimum of fifty percent (50%) of patients within four weeks of the treatment outcome discussion
- All required protocols are in place

Bibliography

1. Spatz H, Engel J, Holzel D, Jauch KW. The surgical discharge summary: A lack of substantial clinical information may affect the postop treatment of rectal cancer patients. *Langenbecks Arch Surg.* 2001;386(5): 350-356.



Definition and Requirements

The NAPRC-accredited program must present and discuss patients with rectal cancer with the Rectal Cancer Multidisciplinary Team (RC-MDT) before the initiation of neoadjuvant therapy. This requirement is outlined in Standard 5.6.

A minimum of ninety percent (90%) of patients with rectal cancer who undergo neoadjuvant therapy at the NAPRCaccredited program must also be presented and discussed by the RC-MDT after the completion of neoadjuvant therapy. This RC-MDT presentation and discussion must include the review of a post-treatment MRI. The post-treatment MRI results must be read and recorded as outlined in Standard 5.4 and must be included in the patient medical record.

Patients being considered for clinical management under a watch and wait protocol must be approved by the RC-MDT and managed in accordance with the NAPRC-accredited program's watch and wait protocol. The requirements for the management of patients under a watch and wait protocol are outlined in Standard 5.13.

Documentation

Reviewed During the Site Visit

• The site reviewer will evaluate pre-selected medical records to confirm compliance with the standard

Measure of Compliance

The NAPRC-accredited program fulfills all compliance criteria:

• Following neoadjuvant therapy, a minimum of ninety percent (90%) of patients are presented and discussed by the RC-MDT, which includes the review of a post-treatment MRI

5.13 Watch and Wait Protocol

Definition and Requirements

Following neoadjuvant therapy, patients with a favorable prognosis may be candidates for organ-preservation and monitored under a watch and wait protocol.

NAPRC-accredited programs are not required to develop and implement a watch and wait protocol as a treatment modality, but compliance with this standard must be met when watch and wait management is utilized.

The NAPRC-accredited program must determine eligibility criteria to identify patients as appropriate candidates for clinical management under a watch and wait protocol following the completion of neoadjuvant therapy. The specific eligibility criteria are determined locally by the Rectal Cancer Multidisciplinary Team (RC-MDT) and must be documented in the NAPRC-accredited program's watch and wait protocol.

Candidates for clinical management under the watch and wait protocol must be approved by the RC-MDT. Documentation of clinical management under the watch and wait protocol must be included in the patient medical record.

Watch and wait candidates must be presented and discussed by the RC-MDT. The RC-MDT presentation must include the review of post-treatment MRI images and post-treatment endoscopy images. If post-treatment MRI and endoscopy images are not available, new images must be obtained by the NAPRC-accredited program prior to RC-MDT presentation. Post-treatment endoscopy images must be presented and discussed by the RC-MDT for a minimum of fifty percent (50%) of watch and wait candidates. The Appendix of Optimal Resources for Rectal Cancer Care (2026 Standards) includes a reference table for the review of post-treatment endoscopy images during the RC-MDT presentation and discussion. The RC-MDT presentation must include complete local re-staging using the post-treatment MRI images and endoscopy images. If PET scans have been performed as part of the patient assessment, the PET scans must also be reviewed by the RC-MDT.

The NAPRC-accredited program must develop and implement a protocol for the clinical management of patients approved for watch and wait surveillance. At a minimum, the protocol must address the following topics, including, but not limited to:

- Eligibility criteria for proceeding with watch and wait surveillance, including any contraindications to watch and wait surveillance (for example, patient availability for follow-up)
- Presentation and approval of watch and wait candidates by the RC-MDT, including review of post-treatment MRI and endoscopy images, and complete local re-staging
- Documentation of all specific clinical processes associated with watch and wait surveillance
- Frequency of follow-up appointments and assessments, as indicated by the RC-MDT
- Consideration for follow-up imaging, such as MRI, CT scans and/or PET scans, and endoscopy
- The providers (either individually or by specialty) responsible for reviewing follow-up imaging and patient clinical assessment
- Specific mechanisms for patient follow-up and patient tracking, to minimize patients being lost to follow-up while under the watch and wait surveillance protocol

The NAPRC has set no specific requirements for the clinical management of patients under watch and wait surveillance (for example, the time interval between neoadjuvant therapy and watch and wait surveillance; candidacy assessment; the time intervals between follow-up appointments and/or follow-up imaging). These decisions must be made locally by the RC-MDT and the treating physicians following appropriate clinical care pathways and documented in the NAPRC-accredited program's watch and wait protocol.

Discordant results between MRI and endoscopy imaging must be reviewed by the treating physician(s) and documented in the patient medical record.

Patients managed under the watch and wait protocol are not required to be re-presented for discussion by the RC-MDT after each routine follow-up appointment. Patients managed under the watch and wait protocol must be re-presented for discussion by the RC-MDT in the event of a significant clinical finding from any follow-up assessment or imaging study. If a patient managed under the watch and wait protocol requires surgical intervention performed by the NAPRCaccredited program, the patient's evaluation and treatment must meet compliance with the following NAPRC Standards:

- Standard 5.3 Systemic Staging with Computerized Tomography
- Standard 5.4 Local Staging and Standardized Reporting with Magnetic Resonance Imaging
- Standard 5.6 Treatment Planning Discussion and Recommendation Summary
- Standard 5.8 Surgical Resection and Standardized Operative Reporting
- Standard 5.9 Pathology Reports after Surgical Resection
- Standard 5.10 Specimen Photographs

Documentation

Submitted with the Pre-Review Questionnaire

• The required protocol for the clinical management and follow-up of patients under watch and wait surveillance

Measure of Compliance

The NAPRC-accredited program fulfills all compliance criteria:

- A protocol is in place for managing patients under watch and wait surveillance, including eligibility criteria and contraindications for watch and wait surveillance, and patient presentation and approval for watch and wait surveillance by the RC-MDT
- Post-treatment endoscopy images are presented and discussed by the RC-MDT for a minimum of fifty percent (50%) of watch and wait candidates
- Patients under watch and wait surveillance receive necessary follow-up care, including any required follow-up imaging, review of discordant imaging results, and representation for discussion by the RC-MDT in the event of a significant clinical finding

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6

Data Surveillance and Systems

Rationale

High-quality data are critical to inform quality improvement and measure the performance of programs. All required cases must be submitted to the National Cancer Database (NCDB) using nationally standardized data item and coding definitions.

Data are validated through multiple mechanisms that are continuously updated to optimize the quality of the data collected.

Fulfilled by the Commission on Cancer standard requirements.


7

Quality Improvement

Rationale

In support of quality improvement efforts, the NAPRCaccredited program must develop a culture of collaboration in order to analyze and implement strategies based on data to drive improvement in the quality of care. Continuous quality improvement must be reflected in the results of such efforts.

7.1 Quality Measures

Definition and Requirements

The National Accreditation Program for Rectal Cancer (NAPRC) requires accredited programs to treat patients with cancer according to nationally accepted quality measures indicated by the National Cancer Database (NCDB) quality reporting tools.

The RC-MDT must monitor the NAPRC-accredited program's expected Estimated Performance Rates (EPR) for quality measures selected annually by the NAPRC. Details on the quality measures for this standard may be referenced on the NCDB website and/or NAPRC Quality Portal, which includes quality measure specifications, years for performance evaluation, and quality measure performance thresholds for this standard. Performance rates for these quality measures will be extracted from the NCDB reporting tools.

If the NAPRC-accredited program is not meeting the expected EPR of a quality measure(s), then a corrective action plan must be developed and implemented in order to improve performance. The corrective action plan must document how the program will investigate the issue(s) for each quality measure with the goal of resolving all barriers and improving compliance.

The Rectal Cancer Multidisciplinary Team's (RC-MDT) review of compliance with required quality measures and monitoring activity must be documented in the RC-MDT meeting minutes. Any action plans and corrective action taken must be included in the documentation.

NAPRC-accredited programs with no cases eligible for assessment in a selected quality measure are exempt from requirements for that individual measure.

Documentation

Submitted with Pre-Review Questionnaire

• RC-MDT meeting minutes documenting the presentation and review of required quality measures, including documentation for any required corrective action plans

Documentation uploaded into the Pre-Review Questionnaire must have all protected health information removed.

It is expected that programs follow local, state, and federal requirements related to patient privacy, risk management, and peer review for all standards of accreditation. These requirements vary state-to-state.

Measure of Compliance

Each calendar year, the NAPRC-accredited program fulfills all compliance criteria:

- The RC-MDT monitors the program's expected Estimated Performance Rates for quality measures selected by the NAPRC
- The monitoring activity is documented in the RC-MDT meeting minutes
- For each quality measure selected by the NAPRC, the quality reporting tools show a performance rate equal to or greater than the expected Estimated Performance Rate specified by the NAPRC
- If the expected Estimated Performance Rate is not met, the program has implemented a corrective action plan that reviews and addresses program performance below the expected EPR

Bibliography

1. National Cancer Database. CoC Quality Measure Development. Available at: <u>https://www.facs.org/quality-programs/cancer-programs/national-cancer-database/quality-of-care-measures/</u>. Accessed July 1, 2024.

.2 Quality Improvement Initiative

Definition and Requirements

Under the guidance of the Rectal Cancer Program (RCP) Director, the NAPRC-accredited program must measure, evaluate, and improve its performance through at least one rectal cancer-specific quality improvement initiative each calendar year. The NAPRC quality improvement initiative must be separate and distinct from the quality improvement initiative implemented to demonstrate compliance with CoC Standard 7.3: Quality Improvement Initiative.

This quality improvement (QI) initiative requires the NAPRCaccredited program to identify a problem, understand the root cause of the identified problem through the use of a recognized performance improvement methodology, and implement a planned intervention to the problem. Reports on the status of the QI initiative must be given to the RC-MDT at least twice each calendar year and documented in the RC-MDT meeting minutes.

Required Components for Quality Improvement Initiatives 1. Review Data to Identify the Problem

The QI initiative must be focused on an already identified, quality-related problem specific to the NAPRC-accredited program.

The following may be used to identify the focus of the QI initiative:

- Problems identified in a National Cancer Database (NCDB) quality measure
- Problems identified through review of NCDB data, including Cancer Quality Improvement Program (CQIP)
- Data-focused quality problems identified through a chart review of a specific cohort of patients in order to assess an area of specific concern or to assess an area of care specified in nationally recognized guidelines
- Data-focused quality problems identified through an internal institution-specific or health-system-specific database, which may include the entire cancer registry or a smaller established clinical database
- Problems identified through review of data related to cultural competency, individualized shared decision making, and the implementation of health equity interventions in the cancer program

• Any other rectal cancer-specific, quality-related problem identified by the RC-MDT

2. Write the Problem Statement

The QI initiative must have a problem statement. The problem statement must outline:

- A specific, already identified, quality-related problem that is specific to the NAPRC-accredited program to solve through the QI initiative
- The baseline and goal metrics (must be numerical)
- The anticipated timeline for completing the QI initiative, and achieving the expected outcome

The problem statement for the QI initiative cannot state that a study is being done to see if a problem exists. The problem must already be known to exist.

3. Choose and Implement Performance Improvement Methodology and Metrics

The RCP Director and RC-MDT must identify the subject matter experts needed to execute the QI initiative. A recognized, standardized performance improvement methodology must be selected and implemented to conduct the QI initiative (for example, Lean, DMAIC, or PDCA/PDSA).

In line with the performance improvement methodology selected, the team must conduct analysis to identify all possible factors contributing to the problem. This may involve literature review and/or root-cause analyses. Based on the results of this analysis, an intervention must be developed that aims to fix the cause of the problem being studied.

It is recommended to establish a project calendar, which includes the launch date of the QI initiative, when status updates will be given at RC-MDT meetings, and a project end date.

QI initiatives are expected to last approximately one calendar year. If additional time is required, the initiative may be extended for a second year (for a total of two years). However, a new QI initiative must be started at the beginning of each calendar year, even if a previous QI initiative is still in progress. The last RC-MDT meeting of the calendar year must include a status update for any ongoing QI initiative that will be extended into a second calendar year. 4. **Implement Intervention and Monitor Data** The intervention chosen in step three must be implemented. If oversight of the implementation suggests the intervention is not working, then it must be modified.

5. Present Quality Improvement Initiative Summary

Once the initiative has been completed, a document summarizing the initiative and the results must be presented and discussed with the RC-MDT and documented in the RC-MDT meeting minutes. The results of the QI initiative must be quantifiable, using outcomes data compared to the baseline data and the numerical goal metrics established in step two. The results of the QI initiative must also be compared with national benchmark data, whenever possible.

The summary presentation must include:

- Summary of the data reviewed to identify the problem that was studied
- The problem statement
- The QI initiative team members
- Performance improvement methodology utilized
- The implemented intervention(s)
- If applicable, any adjustments made to the intervention(s)
- Results of the implemented intervention(s)

RC-MDT Reports

The RCP Director and/or the quality improvement team must provide updates to the RC-MDT on the QI initiative's status at least twice each calendar year. Status updates, at a minimum, indicate the current status of the QI initiative and any planned next steps. The final summary and results report may qualify as one of the required reports.

Documentation

Reviewed During the Site Visit

• Documentation of QI initiative team's work from throughout the initiative (for example, meeting minutes, literature used)

Submitted with Pre-Review Questionnaire

- Quality Improvement Initiative Template
- RC-MDT meeting minutes documenting required status updates and presentation of the QI initiative summary

Documentation uploaded into the Pre-Review Questionnaire must have all protected health information removed.

It is expected that programs follow local, state, and federal requirements related to patient privacy, risk management, and peer review for all standards of accreditation. These requirements vary state-to-state.

Measure of Compliance

The NAPRC-accredited program fulfills all compliance criteria:

- One quality improvement initiative based on an identified quality-related problem is initiated each calendar year. The QI initiative documentation includes how it measured, evaluated, and improved performance through implementation of a recognized, standardized performance improvement methodology
- Status updates are provided to the RC-MDT two times. Reports are documented in the RC-MDT meeting minutes
- A final presentation of a summary of the quality improvement initiative is presented after the QI initiative is complete. The summary presentation includes all required elements

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8

Education: Professional and Community Outreach

Rationale

The success of the NAPRC-accredited program may vary based on the capability of the Rectal Cancer Multidisciplinary Team (RC-MDT) to follow specific principles, which are not uniformly present in the United States. As such, surgeon, radiologist, and pathologist members of the RC-MDT must complete education modules specific to their specialties.

8.1 Rectal Cancer Program Education

Definition and Requirements

Current evidence supports the adoption of four main principles of rectal cancer care: (1) performing surgery that adheres to the principles of total mesorectal excision (TME); (2) pre-treatment tumor assessment by specialized rectal cancer-protocol Magnetic Resonance Imaging (MRI) to identify patients at high risk for local tumor recurrence who may benefit from neoadjuvant therapies; (3) specific techniques of pathology assessment of the resected rectum that contribute to patient prognosis, need for adjuvant chemotherapy, and evaluation of the quality of surgery; and (4) a multidisciplinary team approach that identifies, coordinates, delivers, and monitors the ideal treatment for each individual patient.

The success of a rectal cancer program may vary based on the capability of a facility's Rectal Cancer Multidisciplinary Team (RC-MDT) to follow the above principles. The skills required to fulfill these principles, however, are not uniformly present in the United States. The completion of education modules designed to train the facility's RC-MDT members in these skill sets is an important requirement for the NAPRC-accredited program.

All surgeon, pathologist, and radiologist physician members of the RC-MDT must complete the relevant National Accreditation Program for Rectal Cancer (NAPRC)-endorsed education module specific to their medical specialties within twelve (12) calendar months of joining the RC-MDT.

Surgery

Sound surgical technique is vital to optimizing oncological outcomes and minimizing complications and morbidity in rectal cancer surgery.

Proctectomy following the principles of TME maintains the integrity of the mesorectal fascial envelope by sharp, direct vision dissection of the plane between the mesorectal fascia and the presacral and endopelvic fascia. The ability of TME to lower local recurrence rates and increase survival has been widely documented.

The training of surgeons and wide implementation of TME has been shown to reduce permanent stoma rates, decrease the incidence of local recurrence, and to improve five-year survival in population-based studies. This NAPRC-endorsed education module was developed by the American Society of Colon and Rectal Surgeons.

Surgeon members of the RC-MDT who perform rectal cancer surgery at the NAPRC-accredited program must complete the NAPRC-endorsed surgery education module at least once. At the discretion of the NAPRC, surgeons may be required to take an updated module in line with clinical advancements.

Pathology

Pathologic assessment of tumor stage and margin status is widely known as the most important prognostic factor in rectal cancer. Pathology grading of the TME specimen has also been shown as an important indicator of surgical quality and resultant oncologic outcomes.

Analysis of the plane of surgery and circumferential resection margin (CRM) status in patients enrolled in a large randomized, controlled trial of preoperative radiotherapy provides evidence for the association between surgical quality and outcomes and the role of the pathologist in surgical quality assessment.

Pathologists who are trained in specialized methods of rectal cancer specimen assessment form an important component of the direct quality assurance of rectal cancer surgery. The College of American Pathologists (CAP) Protocol for the Examination of Resection Specimens From Patients With Primary Carcinoma of the Colon and Rectum is accessible, free of charge, from the CAP website and must be used by pathologists as a self-study. Supplemental education materials are provided by the NAPRC and must be used by pathologists for additional self-study. A signed attestation documenting that the pathologist has reviewed and studied all required materials must be provided by the NAPRC-accredited program. Pathologist members of the RC-MDT who process rectal cancer specimens and report rectal cancer findings at the NAPRC-accredited program must complete the pathology self-study portion of the NAPRC-endorsed education module at least once. At the discretion of the NAPRC, pathologists may be required to take an updated module in line with clinical advancements.

Radiology

Rectal cancer imaging has evolved significantly in the last decade. In Europe, MRI has become the standard for the pre-treatment imaging of rectal cancer based on its accuracy in predicting the CRM, tumor invasion of adjacent pelvic structures, and, to a lesser degree, tumor (T)- and nodal (N)-stage.

Routine use of MRI in the context of a multidisciplinary assessment of rectal cancer has been used to plan neoadjuvant therapy and surgery and has been shown to reduce the incidence of positive circumferential margins. MRI-based treatment planning may also allow for the more efficient use of neoadjuvant therapy, an important factor in potentially reducing both the costs and morbidity of rectal cancer care. This NAPRC-endorsed education module was developed by the American College of Radiology.

Radiologist members of the RC-MDT who review and report rectal cancer imaging at the NAPRC-accredited program must complete the radiology portion of the NAPRC-endorsed education module at least once. At the discretion of the NAPRC, radiologists may be required to take an updated module in line with clinical advancements.

Documentation

Submitted with Pre-Review Questionnaire

• Certificates of completion or signed attestations for the applicable NAPRC-endorsed education modules for each surgeon, pathologist, or radiologist member of the RC-MDT

Measure of Compliance

The NAPRC-accredited program fulfills all compliance criteria:

• All surgeon, pathologist, and radiologist physician members of the NAPRC-accredited program's RC-MDT complete the NAPRC-endorsed education module related to their respective specialty within twelve (12) calendar months of joining the RC-MDT

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Glossary

A

- Accession number: A unique patient identifier assigned when the patient is abstracted in the cancer registry. The accession number consists of the year in which the patient was first seen at the reporting facility and the consecutive order in which the patient was abstracted.
- Accreditation Report: Document released to NAPRC programs at the conclusion of their initial or reaccreditation site visit. The accreditation report includes compliance ratings for each applicable standard and may include specific comments regarding the program's performance. The accreditation report also states the assigned accreditation award and, if applicable, the corrective action due date.
- Accredited Program(s): A medical institution providing comprehensive multidisciplinary care for patients with rectal cancer, which has achieved accreditation by the National Accreditation Program for Rectal Cancer (NAPRC). This also refers to initial applicant programs that are actively pursuing accreditation with the NAPRC.
- ACoS: The American College of Surgeons
- ACoS Cancer Programs: American College of Surgeons' programs focused on improving care and treatment for patients with cancer, including Commission on Cancer, National Accreditation Program for Breast Centers, National Accreditation Program for Rectal Cancer, the National Cancer Database, American Joint Committee on Cancer, and the Cancer Research Program.
- **Analytic cases:** Cases for which the hospital provided the initial diagnosis of cancer and/or for which the hospital contributed to first course of treatment, if those cancers were diagnosed on or after the hospital's reference date and are diseases the Commission on Cancer requires to be abstracted.
- Annually: Once each calendar year.
- **Appeal:** A part of the site visit process where the applicant program contests one (1) or more of the findings of the site visit.
- **Appropriately-credentialed physician:** The Rectal Cancer Program Director has the discretion to delegate certain responsibilities to other physicians on the RC-MDT. Any delegated obligation must be given to a physician whose specialty relates to the subject matter of the audit or other responsibility. For example, a pathologist is recommended to perform the audit for Standard 5.9: Pathology Reports after Surgical Resection.

С

Calendar year: January 1-December 31.

Calendar month: The first day of the month through the last day of the month. For example, March 1 to March 31 or April 1 to April 30.

CoC: Commission on Cancer

- **Compliance:** The accredited program meets all the compliance criteria required for a specific standard.
- **Corrective action:** The process by which a cancer program shows they have met a standard(s) that was non-compliant at the time of the site visit.

D

Definitive treatment: Neoadjuvant therapy, surgical resection, local excision when initiated as definitive treatment, or the initiation of palliative care.

Ε

Elsewhere: A hospital, facility, or health care organization that is not owned, co-owned, or part of the accredited facility. A network clinic or outpatient center owned by the facility is part of the facility.

I

- **"In Development" Standard:** Standards and information that have components that are still in development by the NAPRC or its partners. Programs will not be held to components of the compliance requirements for these standards until an official announcement by the NAPRC. Further details, clarifications, and updates regarding these standards and NAPRC policies are provided on the <u>NAPRC</u> website and/or in the <u>Quality Portal</u>.
- **Initial applicants for NAPRC accreditation:** NAPRC standards with requirements that must be met on an annual basis are evaluated for compliance following a rolling twelve (12) month review period.

Μ

Medical record review: The review of pre-selected patient medical records to determine compliance with specific standard requirements.

Ν

NAPRC: National Accreditation Program for Rectal Cancer

- NAPRC-accredited program(s): A medical institution providing diagnostic services, treatment services, and comprehensive multidisciplinary care for patients with rectal cancer, which has achieved accreditation by the National Accreditation Program for Rectal Cancer (NAPRC).
- **Non-compliance:** The NAPRC-accredited program does not meet one (1) or more of the compliance criteria required for a specific standard.

0

On-site: The NAPRC-accredited program's facility or offcampus location(s) that are either owned by its facility or part of the program's accreditation.

Ρ

- **Pre-Review Questionnaire (PRQ):** An online reporting tool that is utilized to demonstrate compliance with NAPRC standards.
- **Previously undiagnosed:** Patients with rectal cancer who receive the first diagnosis of rectal cancer at the rectal cancer program.
- **Previously untreated:** Patients with rectal cancer who have received no treatment for rectal cancer.
- **Programs renewing NAPRC accreditation:** NAPRC standards with requirements that must be met on an annual basis require documentation of compliance during each full calendar year (January 1 December 31) of the accreditation review period.
- Protocol: Previously referred to as "policies and procedures" in the previous version of the NAPRC Standards, a protocol is a structured and consistent process crafted by the NAPRC-accredited program to help implement the required compliance criteria for specific NAPRC standards. Protocols must be written and documented in a manner that demonstrates compliance with whichever NAPRC standard the protocol is designed to address. Additionally, all protocols must be formally approved by the Rectal Cancer Multidisciplinary Team (RC-MDT). Protocols do not need to be officially-recognized hospital or institutional policies. PRQ: See "Pre-Review Questionnaire"

R

RCP: Rectal Cancer Program

RCP Director: Rectal Cancer Program Director. See definition and requirements in Standard 2.2.

- **Referred services:** Components of evaluation and management not under the control or accountability of the rectal cancer program and/or its facility.
- **RC-MDT:** Rectal Cancer Multidisciplinary Team. See definition and requirements in Standard 2.1.

RCP Coordinator: Rectal Cancer Program Coordinator. See definition and requirements in Standard 2.3.

S

Site Visit: A virtual or in-person site visit by a NAPRC Site Reviewer to review cancer program data to aid in determining compliance with NAPRC standards and the respective accreditation award. After initial accreditation, the site visit occurs once every three years.

Site Reviewer: NAPRC-trained physician who conducts site visits and reviews the compliance documentation of a NAPRC-accredited program. The site reviewer assists in verifying whether the accredited program meets compliance with the NAPRC Standards.

- **Standard:** Qualification criteria for NAPRC accreditation (not standard of care).
- **Survey/Surveyor:** Retired terminology. See "Site Visit" and "Site Reviewer".
- **Synoptic format:** A structured format that includes all of the following:
 - All core elements must be reported (whether applicable or not)
 - All core elements must be reported in a "diagnostic parameter pair" format, in other words, data element followed by its response (answer)
 - Each diagnostic parameter pair must be listed on a separate line or in a tabular format to achieve visual separation
 - All core elements must be listed together in one location in the radiology, pathology, or operative report



Appendix

Required Elements for Standardized Synoptic Reporting: MRI Local Excision Procedure Assessment (Standard 5.4)

Clinical Information:

Procedure Date: [] Procedure Type: [Endoscopic polypectomy/TAE/TAMIS/TEMS/ESD/EMR/NA] Procedure Location: [____cm from anal verge/NA] Tattoo placed: [Y/N] Endo-clip in place? [Y/N] Procedure Histology: [HGD or invasive cancer only intramucosal (TIS)/invasive cancer involves SM (T1) +/- positive margin/LVI or incomplete polypectomy/NA] Technique: Multiplanar, multisequence imaging of the pelvis. Magnet strength: [] IV gadolinium contrast: [] Comparison: [] Rectal Wall: EXCISION SITE/MUCOSAL ABNORMALITY: MRI-T2W: □ No Focal abnormality seen □ Focal abnormality as follows □ Scar present □ Scar and possible residual tumor (mass-like or polypoid intermediate signal intensity or mucin signal intensity in wall) □ Residual tumor/mass Equivocal finding between residual tumor and post-procedural change DWI: (with associated low ADC) - restricted diffusion and low ADC in tumor or tumor bed □ Present □ Absent □ Artifact/equivocal Distance of the inferior margin of treated tumor/area to the anal verge: [] cm Distance of inferior margin to the top of the sphincter complex/anorectal junction: [] cm Craniocaudal length: [] cm (comment on any change since prior) Maximal wall thickness: [] cm (comment on any change since prior) Lymph Nodes: Mesorectal/superior rectal lymph nodes and/or tumor deposits:

 \Box N0 (no visible lymph node or probably reactive)

 \square N + (Meet Dutch Criteria^{*} see below)

□ Nx (unable to tell reactive vs. malignant nodes)

- Sensitivity of 51 (85%) of 60 (95% CI: 74%, 92%) and a specificity of 216 (97%) of 221 (95% CI: 95%, 99% (Brown G, Richards CJ, Bourne MW, Newcombe RG, Radcliffe AG, Dallimore NS, Williams GT. Morphologic predictors of lymph node status in rectal cancer with use of high-spatial-resolution MR imaging with histopathologic comparison. Radiology. 2003 May;227(2):371-7. doi: 10.1148/radiol.2272011747. PMID: 12732695.)
- 2. Presence of a spiculated border and an indistinct border shows sensitivities of 45 and 36%, and specificities of 100 and 100%, respectively. Presence of a mottled heterogeneic pattern shows a sensitivity of 50%, a specificity of 95%. The presence of these three features were strongly correlated with LN positivity (P < 0.001, respectively). (Kim JH, Beets GL, Kim MJ, Kessels AG, Beets-Tan RG. High-resolution MR imaging for nodal staging in rectal cancer: are there any criteria in addition to the size? Eur J Radiol. 2004 Oct;52(1):78-83. doi: 10.1016/j.ejrad.2003.12.005. PMID: 15380850.)</p>

Extra-mesorectal lymph nodes: any suspicious?

□ No

□ Yes

Extramural Vascular Invasion (EMVI): □ No/□ Yes

Tumor Deposit: □ No/□ Yes

Other: [free text: bones, peritoneal mets, other incidental findings]

Impression:

□ Rectal Wall

*No visualized rectal wall abnormality

* Scar-only is visualized

*Residual soft tissue at excision site

□ Worrisome for residual tumor

Equivocal for tumor

□ Likely post-procedural change

Lymph Nodes

 \square N0 (no visible lymph node or probably reactive)

 \square N + (Meet Dutch Criteria^{*})

□ Nx (unable to tell reactive vs. malignant nodes)

Suspicious Extra-mesorectal lymph nodes: □ No □ Yes (provide location)

*Dutch Baseline Lymph Node Criteria

□ N0 (no visible lymph nodes/deposits)

 \square N+ (short axis >= 9 mm)

□ N+ (short axis 5-9 mm AND at least 2 of the following criteria: round shape/irregular border contour/heterogeneous signal intensity)

□ N+ (short axis < 5 mm AND round shape AND irregular border contour AND heterogeneous signal intensity)

 \Box Nx (all other cases)

Required Elements for Standardized Synoptic Reporting: Surgical Resection (Standard 5.8)

1. ASA score	I; II; III; IV; V	
2. Case status	Elective; urgent (obstructed; bleeding; perforated)	
3. Operation	LAR; APR; TPC	
4. Was the current operation performed for curative intent? Select single best answer.	Yes; no If no: Select single best answer. Diagnostic intent [Narrative Box] Staging intent [Narrative Box] Palliative intent [Narrative Box]	
4. Modality	Open; laparoscopic; hand-assisted laparoscopic; robotic; TES	
5. Location of tumor within rectum	High; middle; low	
6. Height of lower edge of tumor from anal verge	0–20 cm	
7. Mobilization of splenic flexure	Yes; no	
8. Level of ligation of inferior mesenteric artery	IMA; SRA; none	
9. Level of ligation of inferior mesenteric vein	High; low; none	
10. Level of rectal transection distal to distal edge of tumor' (distal margin)	0–20 cm	
11. Type of reconstruction	Stapled end-end; stapled end-side; handsewn end-end; handsewn end-side; colon J-pouch; ileal pouch-anal anastomosis; coloplasty; none	
12. Anastomotic testing method(s)	Rectal air infusion under pelvic fluid; rectal instillation of betadine, indigo, or other fluid; palpation; observation of circular stapler rings only; none	
13. Creation of Stoma	Yes (ileostomy; colostomy); no	
14. En bloc resection	Yes (bladder; vagina; prostate; ureter; small intestine; sacrum; other); no	
15. Metastasectomy	Yes (live; peritoneum; other); no	
16. Completeness of tumor resection	R0; R1; R2	
17. Intraoperative complications	Yes (ureter injury; rectal perforation; enterotomy; vascular injury; other); no	
18. Blood transfusion	Yes; no	
19. TME photographed	Yes—in pathology report; yes—in operative report; no	
20. Short narrative	***	

Required Elements for Standardized Synoptic Reporting: Local Excision (Standard 5.8)

Section 1: EMR Autopopulated Information

- Patient Name*
- Patient ID*
- Date of Surgery*
- Name of Surgeon*
- Name of Co-Surgeon
- Name of Assistant(s)
- Indication for Surgery*
- Preoperative Diagnosis*
- Postoperative Diagnosis*
- Procedure(s) Performed*
- Specimens Removed
- Type of Anesthesia
- Estimated Blood Loss

Additional Administrative Details (not autopopulated by EHR)

- Indication for Surgery
 - □ Initial diagnostic procedure
 - □ Excision of malignant polyp/malignancy
 - □ Re excision of malignant polypectomy site/malignancy
- Preoperative Diagnosis
 - □ Benign neoplasm/lesion rectum (T0)
 - □ Malignant neoplasm rectum
 - Pretreatment Clinical T Staging
 - 🗖 T1-2
 - □ T3
 - Unknown T [narrative box]
 - Pretreatment Clinical N Staging
 - □ N0
 - □ N+
 - □ Unknown N [narrative box]
 - □ Other, indeterminate [narrative box]

Section 2: Cancer specific Information

Intent of Surgery

Was the operation performed for curative intent?

□ Yes

□ No (If no: Select single best answer)

□ Initial histologic diagnostic intent

□ Re-excision of incompletely excised neoplasm

□ Rectal cancer regrowth

Definitive palliative intent

Preoperative Neoplasm Location

Level of neoplasm in rectum

□ Low Rectum (0-5cm)

□ Mid Rectum (5.1-10cm)

□ Upper Rectum (10.1-15cm)

Level as measured by:

□ Procto/Flex sig

🗖 MRI

DRE DRE

□ Other [narrative box]

Height of lower edge of neoplasm

____ (0-15) cm from

□ anal verge

□ dentate line

Height as measured by:

□ Procto/Flex sig

🗖 MRI

DRE DRE

□ Other [narrative box]

Gross size of initial neoplasm (greatest dimension)

____ (0-15) cm

Size as measured by: Select single best answer.

□ Procto

🗖 MRI

DRE DRE

□ Unable to determine [narrative box]

Sphincter involvement

 \Box Involving the anal sphincter

□ Not involving the anal sphincter

Sphincter involvement determined by:

□ Procto/Flex sig

□ MRI

DRE DRE

□ Other [narrative box]

Primary axial location in the rectum.

□ Right

□ Left

□ Anterior

□ Posterior

□ Circumferential

Relationship to peritoneal reflection [based on MRI]

 \square Below the peritoneal reflection

□ Straddling the peritoneal reflection

 \Box Above the peritoneal reflection

□ MRI not done

□ Unknown

Preoperative therapy

 \Box None

□ Radiation +/- chemotherapy

□ Systemic therapy

□ Total neoadjuvant therapy

Operative Technique

- \Box Conventional transanal excision
- □ Transanal endoscopic surgery (TAMIS, TEMS, TEO)
- □ Robotic transanal excision / robotic TAMIS
- □ Hybrid TAE and TES/Robotic
- □ EMR, ESD (done by MDT surgeon)
- □ Other [narrative box]

Intended gross resection margin

- □ <2mm (other, with explanation) [narrative box]
- □ ~5mm (benign indication)
- □ ~10mm (known or suspected malignancy)

Depth of excision

- □ Full thickness (e.g. known or suspected malignancy)
- □ Partial thickness (e.g. benign indication)
- \square Partial and full thickness

Gross completeness of neoplasm resection

- □ R0
- 🗖 R1
- □ R2

Specimen fragmentation / piecemeal excision

- \square No
- □ Yes

A single view photograph of the specimen should be placed in the medical record by the surgeon or the pathologist

- \Box Yes, in electronic health record
- □ Yes, in report/printed
- \Box Yes, other media
- □ No, reason: [narrative box]

Reference Table for the Review of Post-Treatment Endoscopy Images (Standard 5.13)

It is recommended that the NAPRC-accredited program review post-treatment endoscopy images for candidates of watch and wait surveillance using the reference template below. Use of this reference is not a requirement to meet compliance with Standard 5.13.

Exam	Complete Response	Near Complete Response	Incomplete Response
Digital Rectal Exam	Normal	Smooth induration or minor mucosal abnormalities	Palpable tumor nodules
Endoscopy	Flat, white scar Telangiectasia No ulcer No nodularity	Irregular mucosa Small mucosal nodules or minor mucosal abnormality Superficial ulceration Mild persisting erythema of the scar	Visible tumor



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