

# Colorectal cancer

Quality standard

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This standard is based on NG151.

This standard should be read in conjunction with QS13, QS15, QS81, QS124 and QS134.

## Quality statements

Statement 1 Adults with a new diagnosis of colorectal cancer have testing for Lynch syndrome. [new 2022]

Statement 2 Adults with early rectal cancer discuss the implications of all potential treatment options with their healthcare professional. [new 2022]

Statement 3 Adults with metastatic colorectal cancer suitable for systemic anti-cancer treatment have testing to identify tumours with RAS and BRAF V600E mutations. [new 2022]

Statement 4 Adults who have had potentially curative surgical treatment for non-metastatic colorectal cancer have follow-up for the first 3 years to detect local recurrence and distant metastases. [2012, updated 2022]

In 2022, this quality standard was updated and statements prioritised in 2012 were updated ([2012, updated 2022]) or replaced ([new 2022]). For more information, see [update information](#).

## Related quality statement

Statement 3 on testing for blood in faeces from NICE's quality standard on suspected cancer is relevant to this quality standard and should also be considered when commissioning or providing colorectal cancer services.

# Quality statement 1: Testing for Lynch syndrome

## Quality statement

Adults with a new diagnosis of colorectal cancer have testing for Lynch syndrome. [new 2022]

## Rationale

Lynch syndrome is an inherited condition that increases the risk of developing some cancers, including colorectal cancer. A large proportion of people in the UK with Lynch syndrome will be unaware that they have the condition. When adults are first diagnosed with colorectal cancer, testing for mismatch repair proteins on tumours using immunohistochemistry (IHC) or testing for microsatellite instability using polymerase chain reaction (PCR) can guide further testing (including BRAF V600E mutation testing and MLH1 promotor hypermethylation testing) to identify those in whom the cancer may have occurred because of Lynch syndrome. Testing can also inform systemic therapy choices for adults with colorectal cancer. For some cancer sites, risk-reducing strategies can prevent associated cancers or allow their early diagnosis in people with a diagnosis of Lynch syndrome. Testing for Lynch syndrome and offer of cascade testing for family members are included in the [2022/23 priorities and operational planning guidance from NHS England](#).

## Quality measures

The following measures can be used to assess the quality of care or service provision specified in the statement. They are examples of how the statement can be measured, and can be adapted and used flexibly. The process measures follow the testing outlined in [NICE's diagnostics guidance on molecular testing strategies for Lynch syndrome in people with colorectal cancer](#).

## Structure

Evidence of local arrangements to ensure that there is a clinical lead responsible for implementing the testing pathway for Lynch syndrome.

**Data source:** [Cancer Alliances in England](#) have a record of the clinical lead responsible for implementing the testing pathway for Lynch syndrome within regional cancer multidisciplinary teams.

## Process

a) Proportion of adults with a new diagnosis of colorectal cancer who had IHC for mismatch repair proteins or microsatellite instability testing on the tumour.

Numerator – the number in the denominator who had IHC for mismatch repair proteins or microsatellite instability testing on the tumour.

Denominator – the number of adults with a new diagnosis of colorectal cancer.

**Data source:** The [National Disease Registration Service](#) collects data on IHC for mismatch repair proteins and microsatellite instability tests and results from pathology laboratories and genomic laboratory hubs. The [National Bowel Cancer Audit](#) collects patient-level data on performance of mismatch repair protein and microsatellite instability tests.

b) Proportion of adults with a new diagnosis of colorectal cancer and a tumour that shows abnormal MLH1 expression by IHC, or microsatellite instability, who had BRAF V600E mutation testing.

Numerator – the number in the denominator who had BRAF V600E mutation testing.

Denominator – the number of adults with a new diagnosis of colorectal cancer and a tumour that shows abnormal MLH1 expression by IHC, or microsatellite instability.

**Data source:** The [National Disease Registration Service](#) collects data on performance of BRAF V600E mutation testing and results. The [National Bowel Cancer Audit](#) collects data on performance of BRAF V600E mutation tests.

c) Proportion of adults with a new diagnosis of colorectal cancer and a tumour that shows abnormal MLH1 expression by IHC, or microsatellite instability, and a negative BRAF V600E test who had MLH1 promoter hypermethylation testing.

Numerator – the number in the denominator who had MLH1 promoter hypermethylation testing.

Denominator – the number of adults with a new diagnosis of colorectal cancer and a tumour that shows abnormal MLH1 expression by IHC, or microsatellite instability, and a negative BRAF V600E test.

**Data source:** The [National Disease Registration Service](#) collects data on MLH1 promoter hypermethylation testing and results.

d) Proportion of adults with a new diagnosis of colorectal cancer and test results suggestive of Lynch syndrome-associated colorectal cancer who had genetic testing of germline DNA to confirm Lynch syndrome.

Numerator – the number in the denominator who had genetic testing of germline DNA to confirm Lynch syndrome.

Denominator – the number of adults with a new diagnosis of colorectal cancer and test results suggestive of Lynch syndrome-associated colorectal cancer.

**Data source:** The [National Disease Registration Service](#) collects data on the performance of germline testing for Lynch syndrome.

## Outcome

Rate of diagnosis of Lynch syndrome in adults with a new diagnosis of colorectal cancer.

**Data source:** The [National Disease Registration Service](#) collects data on germline testing for Lynch syndrome.

## What the quality statement means for different audiences

**Service providers** (such as histopathology laboratory services, molecular genetics laboratory services or genomic laboratory hubs) ensure that laboratory protocols are in place to provide testing for Lynch syndrome on tumours in adults with a new diagnosis of colorectal cancer. This includes IHC for mismatch repair proteins or microsatellite instability testing, BRAF V600E testing and MLH1 promoter hypermethylation testing. They include results in the standard pathology report requested by oncology. They ensure that laboratory protocols are in place to provide genetic testing of germline DNA for Lynch syndrome in adults with a new diagnosis of colorectal cancer and in whom test results are suggestive of Lynch syndrome.

**Healthcare professionals** (such as gastroenterologists, colorectal surgeons and consultant histopathologists) are aware of local protocols to ensure that adults with a new diagnosis of colorectal cancer have testing for Lynch syndrome. Healthcare professionals are aware of referral

pathways and can identify when to refer to clinical genetics services for the diagnosis of Lynch syndrome.

**Commissioners** (clinical commissioning groups, integrated care systems or NHS England) ensure that they commission services that can provide tests for adults with a new diagnosis of colorectal cancer and genetic tests for those with results that suggest Lynch syndrome-associated cancer.

**Adults with colorectal cancer** have testing to check their tumour for changes that may mean they have Lynch syndrome. If changes are found, they will be offered further tests to be confirm whether or not they have Lynch syndrome. If they do, they can be monitored for other cancers and their close relatives can also be offered testing for Lynch syndrome.

## Source guidance

[Molecular testing strategies for Lynch syndrome in people with colorectal cancer. NICE diagnostics guidance 27 \(2017\), recommendations 1.1 to 1.3](#)

## Definitions of terms used in this quality statement

### Testing for Lynch syndrome

Testing for Lynch syndrome in adults with colorectal cancer uses IHC to test for the expression of MLH1, MSH2, MSH6 and PMS2 proteins or PCR to test for microsatellite instability to identify tumours with deficient DNA mismatch repair. Results from these tests guide further sequential testing for Lynch syndrome. Further testing includes testing for BRAF V600E mutation, and if this is negative, testing for MLH1 promoter hypermethylation. Lynch syndrome can be confirmed by genetic testing of germline DNA. [Adapted from [NICE's diagnostics guidance on molecular testing strategies for Lynch syndrome in people with colorectal cancer](#), recommendations 1.1 to 1.4 and expert opinion]

### Test results suggestive of Lynch syndrome-associated colorectal cancer

Abnormal MLH1 expression by IHC or microsatellite instability, and negative tests for BRAF V600E and MLH1 promoter hypermethylation, or abnormal MSH2, MSH6 or PMS2 expression on IHC. [Adapted from [NICE's diagnostics guidance on molecular testing strategies for Lynch syndrome in people with colorectal cancer](#), recommendations 1.2 and 1.3]



# Quality statement 2: Discussion about treatment options for early rectal cancer

## Quality statement

Adults with early rectal cancer discuss the implications of all potential treatment options with their healthcare professional. [new 2022]

## Rationale

Transanal excision, endoscopic submucosal dissection and total mesorectal excision are potential treatment options for early rectal cancer. There are risks, benefits and possible implications on quality of life associated with each of these treatments. These should be discussed with their healthcare professional as well as personal preferences and practical factors before reaching a shared decision about the best option. A discussion about treatment options also offers the opportunity for adults with early rectal cancer to be given information on non-surgical procedures, the option of no treatment and participation in clinical trials.

## Quality measures

The following measures can be used to assess the quality of care or service provision specified in the statement. They are examples of how the statement can be measured, and can be adapted and used flexibly.

## Structure

Evidence of availability of information to support discussions about all potential treatment options for adults with early rectal cancer.

**Data source:** No routinely collected national data for this measure has been identified. Data could be collected from information recorded locally by healthcare professionals, for example the availability of resources to help prepare for discussing options and making shared decisions. The [National Bowel Cancer Audit](#) organisational survey in 2022 will include a question at provider level on whether written information on different treatment options is provided to adults with rectal cancer.

## Process

Proportion of adults with early rectal cancer who had a discussion about all potential treatment options with their healthcare professional.

Numerator – the number in the denominator who had a discussion about all potential treatment options with their healthcare professional.

Denominator – the number of adults with early rectal cancer.

**Data source:** No routinely collected national data for this measure in adults with early rectal cancer has been identified. Data can be collected from information recorded locally by healthcare professionals, for example from patient records. The [National Cancer Patient Experience Survey](#) includes a question that asks if treatment options were discussed with the person with colorectal cancer before cancer treatment started, but this is not limited to those with early rectal cancer.

## What the quality statement means for different audiences

**Service providers** (such as secondary care services and specialist tertiary care services) ensure that staff are aware of all potential treatment options for early rectal cancer and are trained to discuss the implications of each treatment before they reach a shared decision with adults with early rectal cancer about the best option for them. Service providers ensure that adults with early rectal cancer have the option to be referred to another service provider if they do not offer a particular treatment option.

**Healthcare professionals** (such as colorectal cancer specialists) clearly explain all potential treatment options for early rectal cancer including endoscopic procedures, minimally invasive local surgical procedures and rectal resection. They give information on non-surgical procedures, the option of no treatment and relevant clinical trials. They discuss the implications of each of the options with adults with early rectal cancer before reaching a shared decision about the best option for them.

**Commissioners** (such as clinical commissioning groups, integrated care systems or NHS England) ensure that they commission services that can provide all potential treatment options for adults with early rectal cancer, including endoscopic and minimally invasive procedures, or have pathways in place to refer to other providers.

Adults with early rectal cancer have a discussion with their healthcare professional about all potential treatments, including no treatment, and are given information about procedures that do not need surgery. They feel informed to reach a decision about the best option for them.

## Source guidance

Colorectal cancer. NICE guideline NG151 (2020, updated 2021), recommendations 1.2.2 and 1.3.1

## Definitions of terms used in this quality statement

### Early rectal cancer

Rectal cancer at stage cT1-T2, cN0, M0. [[NICE's guideline on colorectal cancer](#), recommendation 1.3.1]

### Treatment options for early rectal cancer

Transanal excision including transanal minimally invasive surgery and transanal endoscopic microsurgery, endoscopic submucosal dissection or total mesorectal excision. [[NICE's guideline on colorectal cancer](#), table 1]

## Equality and diversity considerations

Adults with early rectal cancer should be provided with information that they can easily read and understand themselves, or with support, so they can communicate effectively with health and social care services. Information should be in a format that suits their needs and preferences. It should be accessible to those who do not speak or read English, and it should be culturally appropriate and age appropriate. Adults with early rectal cancer should have access to an interpreter or advocate if needed.

For people with additional needs related to a disability, impairment or sensory loss, information should be provided as set out in [NHS England's Accessible Information Standard](#) or the equivalent standards for the devolved nations.

# Quality statement 3: Testing to guide systemic anti-cancer treatment

## Quality statement

Adults with metastatic colorectal cancer suitable for systemic anti-cancer treatment have testing to identify tumours with RAS and BRAF V600E mutations. [new 2022]

## Rationale

Predictive biomarkers provide information about the effects of a therapeutic intervention on patient outcomes. They can therefore help to guide treatment decision making. Testing for RAS and BRAF V600E mutations is used to select adults with metastatic colorectal cancer who are most likely to benefit from targeted therapy.

## Quality measures

The following measures can be used to assess the quality of care or service provision specified in the statement. They are examples of how the statement can be measured, and can be adapted and used flexibly.

## Structure

Evidence of local arrangements and clinical protocols to ensure that adults with metastatic colorectal cancer suitable for systemic anti-cancer treatment have testing to identify tumours with RAS and BRAF V600E mutations.

**Data source:** No routinely collected national data for this measure has been identified. Data can be collected from information recorded locally by healthcare professionals and provider organisations, for example written clinical protocols. The [National Bowel Cancer Audit](#) plans to report on RAS and BRAF testing at provider level.

## Process

Proportion of adults with metastatic colorectal cancer suitable for systemic anti-cancer treatment who had testing to identify tumours with RAS and BRAF V600E mutations.

**Numerator** – the number in the denominator who had testing to identify tumours with RAS and BRAF V600E mutations.

**Denominator** – the number of adults with metastatic colorectal cancer suitable for systemic anti-cancer treatment.

**Data source:** The [National Disease Registration Service](#) collects data on RAS and BRAF testing. The [National Bowel Cancer Audit](#) collects patient-level data on the performance of RAS and BRAF V600E tests in stage IV disease.

## Outcome

Progression-free survival for adults with metastatic colorectal cancer suitable for systemic anti-cancer treatment.

**Data source:** No routinely collected national data for this measure has been identified. Data can be collected routinely from information recorded locally by healthcare professionals and provider organisations, for example from patient records.

## What the quality statement means for different audiences

**Service providers** (such as laboratory services) ensure that systems are in place to provide testing to identify tumours with RAS and BRAF V600E mutations in adults with metastatic colorectal cancer suitable for systemic anti-cancer treatment.

**Healthcare professionals** (such as oncologists) are aware of local referral pathways for testing to identify tumours with RAS and BRAF V600E mutations in adults with metastatic colorectal cancer suitable for systemic anti-cancer treatment.

**Commissioners** (such as clinical commissioning groups, integrated care systems or NHS England) ensure that they commission services that provide testing to identify tumours with RAS and BRAF V600E mutations in adults with metastatic colorectal cancer suitable for systemic anti-cancer treatment.

**Adults with metastatic colorectal cancer suitable for systemic anti-cancer treatment** have testing to identify the most beneficial treatment for them.

## Source guidance

Colorectal cancer. NICE guideline NG151 (2020, updated 2021), recommendation 1.4.1

# Quality statement 4: Follow-up for detecting local recurrence and distant metastases

## Quality statement

Adults who have had potentially curative surgical treatment for non-metastatic colorectal cancer have follow-up for the first 3 years to detect local recurrence and distant metastases. [2012, updated 2022]

## Rationale

Following up adults in the first 3 years after they have had potentially curative surgical treatment for non-metastatic colorectal cancer can help detect and treat recurrences at the earliest stage. Recurrent disease is more likely to be resectable when there is regular follow-up, compared with minimal or no follow-up.

## Quality measures

The following measures can be used to assess the quality of care or service provision specified in the statement. They are examples of how the statement can be measured, and can be adapted and used flexibly.

## Structure

Evidence of local arrangements and written clinical protocols to ensure that adults who have had potentially curative surgery for non-metastatic colorectal cancer have follow-up tests for the first 3 years after treatment.

**Data source:** No routinely collected national data has been identified. Data can be collected from information recorded locally by healthcare professionals and provider organisations, for example written surveillance protocols.

## Process

a) Proportion of adults who had potentially curative surgery for non-metastatic colorectal cancer who had 6-monthly serum carcinoembryonic antigen (CEA) measurement in the 3 years after

potentially curative surgery.

Numerator – the number in the denominator who had 6-monthly serum CEA measurement in the 3 years after potentially curative surgery.

Denominator – the number of adults who had potentially curative surgery for non-metastatic colorectal cancer.

**Data source:** No routinely collected national data for this measure has been identified. Data can be collected from information recorded locally by healthcare professionals and provider organisations, for example from patient records.

b) Proportion of adults who had potentially curative surgery for non-metastatic colorectal cancer who had at least 2 CT scans of the chest, abdomen and pelvis in the 3 years after potentially curative surgery.

Numerator – the number in the denominator who had at least 2 CT scans of the chest, abdomen and pelvis in the 3 years after potentially curative surgery.

Denominator – the number of adults who had potentially curative surgery for non-metastatic colorectal cancer.

**Data source:** No routinely collected national data for this measure has been identified. Data can be collected from information recorded locally by healthcare professionals and provider organisations, for example from patient records.

c) Proportion of adults who had potentially curative surgery for non-metastatic colorectal cancer who had a clearance colonoscopy within 1 year of their diagnosis.

Numerator – the number in the denominator who had a clearance colonoscopy within 1 year of their diagnosis.

Denominator – the number of adults who had potentially curative surgery for non-metastatic colorectal cancer.

**Data source:** No routinely collected national data for this measure has been identified. Data can be collected from information recorded locally by healthcare professionals and provider organisations, for example from patient records.



## Outcome

Proportion of adults with newly diagnosed locally recurrent colorectal cancer after potentially curative surgery for non-metastatic colorectal cancer whose recurrent cancer was resectable at diagnosis.

**Numerator** – the number in the denominator whose recurrent cancer was resectable at diagnosis.

**Denominator** – the number of adults with newly diagnosed locally recurrent colorectal cancer after potentially curative surgery for non-metastatic colorectal cancer.

**Data source:** Data can be collected from information recorded locally by healthcare professionals and provider organisations, for example from patient records.

## What the quality statement means for different audiences

**Service providers** (such as laboratory services, secondary care services and tertiary care centres) ensure that systems are in place for adults who have had potentially curative surgery for non-metastatic colorectal cancer to have follow-up testing, including serum CEA, CT scan and colonoscopy, in the first 3 years after potentially curative surgery.

**Healthcare professionals** (such as colorectal cancer nurse specialists) are aware of local pathways and clinical protocols for follow-up of adults who have had potentially curative surgery for non-metastatic colorectal cancer. They ensure that these adults have regular testing of serum CEA, CT scans and colonoscopy in the first 3 years after potentially curative surgery.

**Commissioners** (such as clinical commissioning groups, integrated care systems and NHS England) ensure that they commission services that provide regular follow-up of adults after potentially curative surgery for colorectal cancer, including measurement of serum CEA, CT scan and colonoscopy.

**Adults with colorectal cancer that has not spread to other parts of their body and who have had surgery that may cure their cancer** have regular check-ups and investigations for the first 3 years to check for signs that the cancer has returned or has spread.

## Source guidance

- [Colorectal cancer. NICE guideline NG151](#) (2020, updated 2021), recommendation 1.6.1
- [BSG/ACPGBI/PHE post-polypectomy and post-colorectal cancer resection surveillance guidelines](#) (2020), page 207

The frequency of measurement of CEA, CT scan and colonoscopy used in process measures a), b) and c) are considered practical measures to enable cancer networks to measure performance. The frequencies in process measures a) and b) are taken from NICE's guideline on colorectal cancer, evidence review E1. The frequency for colonoscopy in process measure c) is used in BSG/ACPGBI/PHE post-polypectomy and post-colorectal cancer resection surveillance guidelines (2020), page 207.

## Definitions of terms used in this quality standard

### Follow-up to detect local recurrence and distant metastases

Follow-up includes measurement of serum CEA at least every 6 months and a minimum of 2 CT scans of the chest, abdomen and pelvis in the first 3 years. Clearance colonoscopy should be done within a year of diagnosis. [Adapted from [NICE's guideline for colorectal cancer](#), recommendation 1.6.1 and evidence review E1 and [BSG/ACPGBI/PHE post-polypectomy and post-colorectal cancer resection surveillance guidelines](#) (2020), page 207]

## Update information

**February 2022:** This quality standard was updated and statements prioritised in 2012 were replaced. The topic was identified for update following the annual review of quality standards. The review identified:

- updated guidance on colorectal cancer.

Statements are marked as:

- **[new 2022]** if the statement covers a new area for quality improvement
- **[2012, updated 2022]** if the statement covers an area for quality improvement included in the 2012 quality standard and has been updated.

Statement number 8 in the 2012 version has been updated and is included in the updated quality standard, marked as **[2012, updated 2022]**.

## About this quality standard

NICE quality standards describe high-priority areas for quality improvement in a defined care or service area. Each standard consists of a prioritised set of specific, concise and measurable statements. NICE quality standards draw on existing NICE or NICE-accredited guidance that provides an underpinning, comprehensive set of recommendations, and are designed to support the measurement of improvement.

Expected levels of achievement for quality measures are not specified. Quality standards are intended to drive up the quality of care, and so achievement levels of 100% should be aspired to (or 0% if the quality statement states that something should not be done). However, this may not always be appropriate in practice. Taking account of safety, shared decision-making, choice and professional judgement, desired levels of achievement should be defined locally.

Information about [how NICE quality standards are developed](#) is available from the NICE website.

See our [webpage on quality standards advisory committees](#) for details of standing committee 2 members who advised on this quality standard. Information about the topic experts invited to join the standing members is available from the [webpage for this quality standard](#).

NICE has produced a [quality standard service improvement template](#) to help providers make an initial assessment of their service compared with a selection of quality statements. This tool is updated monthly to include new quality standards.

NICE guidance and quality standards apply in England and Wales. Decisions on how they apply in Scotland and Northern Ireland are made by the Scottish government and Northern Ireland Executive. NICE quality standards may include references to organisations or people responsible for commissioning or providing care that may be relevant only to England.

## Resource impact

NICE quality standards should be achievable by local services. The potential resource impact is considered by the quality standards advisory committee, drawing on resource impact work for the source guidance. Organisations are encouraged to use the resource impact products for the source guidance to help estimate local costs:

- [resource impact report and template for NICE's diagnostics guidance on molecular testing strategies for Lynch syndrome in people with colorectal cancer](#)
- [resource impact statement for NICE's guideline on colorectal cancer](#).

## Diversity, equality and language

Equality issues were considered during development and [equality assessments for this quality standard](#) are available. Any specific issues identified during development of the quality statements are highlighted in each statement.

Commissioners and providers should aim to achieve the quality standard in their local context, in light of their duties to have due regard to the need to eliminate unlawful discrimination, advance equality of opportunity and foster good relations. Nothing in this quality standard should be interpreted in a way that would be inconsistent with compliance with those duties.

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## Endorsing organisation

This quality standard has been endorsed by NHS England, as required by the Health and Social Care Act (2012)

## Supporting organisations

Many organisations share NICE's commitment to quality improvement using evidence-based guidance. The following supporting organisations have recognised the benefit of the quality standard in improving care for patients, carers, service users and members of the public. They have agreed to work with NICE to ensure that those commissioning or providing services are made aware of and encouraged to use the quality standard.

- [Bowel Cancer UK](#)
- [Society and College of Radiographers \(SOR\)](#)
- [Royal College of Nursing \(RCN\)](#)
- [Royal College of Physicians and Surgeons of Glasgow](#)