

NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

Guideline scope

Colorectal Cancer (update)

This guideline will update and replace the NICE guideline on [Colorectal cancer: diagnosis and management \(CG131\)](#) and the NICE guideline on [Improving outcomes in colorectal cancer CSG5](#).

The guideline will be developed using the methods and processes outlined in [Developing NICE guidelines: the manual](#).

This guideline will also be used to update the NICE [quality standard](#) for Colorectal cancer (QS20).

1 Why the update is needed

New evidence that could affect recommendations was identified through the surveillance process. Topic experts, including those who helped to develop the existing guideline, advised NICE on whether areas should be updated or new areas added. Full details are set out in the [surveillance review decision CG131 and CSG5](#).

Why the guideline is needed

Key facts and figures

Colorectal cancer (cancer of the colon or rectum, or “bowel cancer”) is the fourth most common cancer in the UK, with over 41,000 new cases diagnosed each year.

Colorectal cancer affects both men and women. Risk factors include increasing age, genetics and family history (particularly syndromes such as familial adenomatous polyposis and Lynch syndrome), inflammatory bowel disease and other dietary and lifestyle factors.

Colorectal cancer is the second most common cause of cancer death in the UK, accounting for 10% of all deaths from cancer and approximately 16,000 deaths each year. Death rates have decreased by 42% overall since the early 1970s.

Survival rates continue to improve. Overall, 76% of people diagnosed with bowel cancer live for at least 1 year, with 59% surviving at least 5 years and 57% for 10 years or more (2010-2011). Survival is linked to disease stage at presentation, with improved survival the earlier the disease is detected and treated.

Current practice

Diagnosis and staging

Diagnosis of colorectal cancer is made using colonoscopy and confirmed histologically by biopsy. Standard practice is to stage all patients for distant metastatic disease. For those with rectal cancer, local tumour staging is done by MRI scan or transrectal ultrasound if MRI is contraindicated.

Local disease

In colon cancer, standard treatment is to offer surgery to those who are fit enough. Locally-advanced colon cancer may be treated with neoadjuvant chemotherapy before surgery. Acute colonic stenting may be offered in cases of malignant large bowel obstruction.

Treating rectal cancer is more complex. Options include surgery alone, preoperative radiotherapy and preoperative chemoradiotherapy. Local excision of the tumour may not be needed after preoperative radiotherapy or chemoradiotherapy. A “watch and wait” approach with no resectional surgery is sometimes used if there is a complete clinical response after chemoradiotherapy.

Metastatic disease

Colorectal cancer is unusual among solid tumours in that metastatic spread to the liver can still be cured with combinations of surgery and chemotherapy. Recently, new chemotherapy drugs have been made available for metastatic

colorectal cancer with the RAS wild-type mutation following a NICE technology appraisal. The chemotherapy pathways developed for the last NICE guideline need to be updated to recognise these changes.

2 Who the guideline is for

People with suspected or diagnosed colorectal cancer or at risk of colorectal cancer due to Lynch syndrome, their families and carers and the public will be able to use the guideline to find out more about what NICE recommends, and help them make decisions.

This guideline is for:

- Health professionals working in secondary care
- Cancer Alliances and cancer clinical networks
- Commissioners of colorectal cancer preventative, diagnostic and treatment services (including Clinical Commissioning Groups and NHS England Specialised Commissioning)

It may also be relevant for:

- Healthcare professionals working in primary care
- People using colorectal cancer services, their family members and carers, and the public
- Private providers
- Voluntary sector organisations working with people with suspected or diagnosed colorectal cancer

NICE guidelines cover health and care in England. Decisions on how they apply in other UK countries are made by ministers in the [Welsh Government](#), [Scottish Government](#) and [Northern Ireland Executive](#).

Equality considerations

NICE has carried out [an equality impact assessment](#) during scoping. The assessment:

- lists equality issues identified, and how they have been addressed

- explains why any groups are excluded from the scope.

The guideline will look at inequalities relating to:

- Older people with long term conditions/co-morbidities. The extent of staging for older people is an issue. This group often receive fewer investigations and have lower surgery rates.

3 What the updated guideline will cover

3.1 *Who is the focus?*

Groups that will be covered

- Adults (18 years and older) with newly diagnosed adenocarcinoma of the colon.
- Adults with newly diagnosed adenocarcinoma of the rectum.
- Adults with relapsed adenocarcinoma of the colon.
- Adults with relapsed adenocarcinoma of the rectum.
- Adults with clinical or genetic evidence of Lynch syndrome [hereditary nonpolyposis colorectal cancer (HNPCC)].

Groups that will not be covered

- People with anal cancer.
- Children and young people aged under 18 years.
- People with primary or secondary lymphoma of the colon and rectum.
- People with pure small cell carcinoma, or other pure neuroendocrine carcinomas, of the colon and rectum.
- People with neuroendocrine tumours of the colon and rectum.
- People with gastrointestinal stromal tumours (GIST) or sarcoma of the colon and rectum.
- People with squamous cells carcinoma of the rectum.
- People with appendiceal neoplasms.

3.2 Settings

Settings that will be covered

- All settings in which NHS commissioned care is provided.

3.3 Activities, services or aspects of care

Key areas that will be covered in this update

We will look at evidence in the areas below when developing this update. We will consider making new recommendations or updating existing recommendations in these areas only.

- 1 Prevention of colorectal cancer
 - Role of aspirin in the prevention of colorectal cancer in adults with clinical or genetic evidence of Lynch syndrome (hereditary nonpolyposis colorectal cancer)
- 2 Molecular biomarkers
 - Use of molecular biomarkers to guide chemotherapy choice
- 3 Management of local disease
 - Rectal cancer
 - Colon cancer
 - Colonic stents for obstructing colon cancer
- 4 Management of metastatic disease
 - Presenting with stage IV colorectal cancer
 - Methods for treating metastasis
- 5 Ongoing care and support
 - Follow-up after apparently curative resection
 - Management of post treatment sequelae
 - Information about managing bowel function
- 6 Service delivery
 - Surgical volumes and rectal cancer surgery

Note that guideline recommendations for medicines will normally fall within licensed indications; exceptionally, and only if clearly supported by evidence, use outside a licensed indication may be recommended. The guideline will

assume that prescribers will use a medicine's summary of product characteristics to inform decisions made with individual patients.

Proposed outline for the guideline

The table below outlines all the areas that will be included in the guideline. It sets out what NICE plan to do for each area in this update.

1.Prevention of colorectal cancer	
NEW Role of aspirin in the prevention of colorectal cancer in adults with clinical or genetic evidence of Lynch syndrome (hereditary nonpolyposis colorectal cancer)	Review evidence: new area in the guideline
2. Molecular biomarkers	
NEW Use of molecular biomarkers in guiding chemotherapy choice	Review evidence: new area in the guideline
3. Management of local disease (some NEW areas focusing separately on rectal and colon cancer)	
Rectal cancer Colon cancer	Review evidence: update existing recommendations from guideline CG131, 1.2.1 – 1.2.1.8 (2011) and 1.2.3.1-1.2.4.4 (2011 & 2014) and 1.2.6.1- 1.2.7.1 (2011) as needed. Recommendations 1.2.5.1 – 1.2.5.3 are based on NICE technology appraisal 105. A link to the NICE Pathway where the TA appears will be added (2006) Recommendations 1.2.8.1-1.2.8.2 are based on NICE technology appraisal 100. A link to the NICE Pathway where the TA appears will be added (2006)
Colonic stents for obstructing colon cancer	Review evidence: update existing recommendations from guideline CG131, 1.2.2.1 – 1.2.2.7 (2011 & 2014) as needed
4. Management of metastatic disease	
Presenting with stage IV colorectal cancer	Review evidence: update existing recommendations from guideline CG131, 1.3.1.1 – 1.3.1.2 (2011) as needed
Methods for treating metastasis	Review evidence: update existing recommendations from guideline CG131, 1.3.4.1 – 1.3.4.4 as needed. Recommendations 1.3.4.5 – 1.3.4.7 are based on NICE technology appraisal 61. A link to the NICE Pathway where the TA appears will be added (2003)
5. Ongoing care and support	
Follow-up after apparently curative resection	Review evidence: update existing recommendations from guideline CG131, 1.4.1.1 – 1.4.1.5 (2011) as needed
NEW Management of post treatment sequelae	Review evidence: new area in the guideline

Information about managing bowel function	Review evidence: update existing recommendations from guideline CG131, 1.4.2.1 – 1.4.2.5 (2011) as needed
6. Service delivery	
NEW Surgical volumes and rectal cancer surgery	Review evidence: new area in the guideline
The following areas from CG131 will not be updated and will be removed from the guideline as there is no longer variation in practice	
Diagnostic investigations	Remove existing recommendations from guideline CG131, 1.1.1.1 – 1.1.1.5 (2011)
Staging of colorectal cancer	Remove existing recommendations from guideline CG131, 1.1.2.1 – 1.1.2.4 (2011)
Imaging of hepatic metastases	Remove existing recommendation from guideline CG131, 1.3.2.1 (2011)
Imaging of extra-hepatic metastases	Remove existing recommendations from guideline CG131, 1.3.3.1 – 1.3.3.6 (2011)
The following areas from CSG5 will not be updated either because they are already covered within scope of update of CG131 <u>or</u> other NICE guidelines <u>or</u> because they are no longer relevant to this guideline.	
Patient centred care	Remove: refer to Patient experience in adult NHS services (2012) NICE guideline CG138
Access to appropriate services	Remove: refer to Suspected cancer: recognition and referral (2015) NICE guideline NG12
Multidisciplinary teams	Remove: see NHS England quality surveillance programme for colorectal cancer
Diagnosis	Remove: there is no longer variation in practice in relation to diagnosis so this section will not be updated and included in the guideline
Surgery and histopathology	Remove: refer to sections 3 and 4 of updated CG131 guideline for recommendations about surgery
Radiotherapy in primary disease	Remove: refer to section 3 of updated CG131 guideline for recommendations about radiotherapy in primary disease

Adjuvant chemotherapy	Remove: refer to section 3 of updated CG131 guideline for recommendations about adjuvant chemotherapy
Anal cancer	Remove: this is out of scope for this update
Follow-up	Remove: refer to section 5 of updated CG131 guideline for recommendations about follow-up
Recurrent and advanced disease	Remove: refer to section 4 of updated CG131 guideline for recommendations about recurrent and advanced disease
Palliative care	Remove: refer to Improving supportive and palliative care for adults with cancer CSG4

Areas not covered by the guideline

- 1 Population screening.
- 2 Colonoscopic surveillance of high-risk groups, including people with a family history of colorectal cancer and people with inflammatory bowel disease.
- 3 Management of anal cancer.

3.4 Related NICE guidance

- [Molecular testing strategies for Lynch syndrome in people with colorectal cancer](#) (2017) NICE guideline DG27
- [Virtual chromoendoscopy to assess colorectal polyps during colonoscopy](#) (2017) NICE guideline DG28
- [Cetuximab and panitumumab for previously untreated metastatic colorectal cancer](#) (2017) NICE technology appraisal guidance TA439
- [Trifluridine–tipiracil for previously treated metastatic colorectal cancer](#) (2016) NICE technology appraisal guidance TA405
- [Cetuximab, bevacizumab and panitumumab for the treatment of metastatic colorectal cancer after first-line chemotherapy: Cetuximab \(monotherapy or combination chemotherapy\), bevacizumab \(in combination with non-oxaliplatin chemotherapy\) and panitumumab \(monotherapy\) for the treatment of metastatic colorectal cancer after first-line chemotherapy](#) (2012) NICE technology appraisal guidance TA242

- [Aflibercept in combination with irinotecan and fluorouracil-based therapy for treating metastatic colorectal cancer that has progressed following prior oxaliplatin-based chemotherapy](#) (2014) NICE technology appraisal guidance TA307
- [Laparoscopic surgery for colorectal cancer](#) (2006) NICE technology appraisal guidance TA105
- [Bevacizumab and cetuximab for the treatment of metastatic colorectal cancer](#) (2012) NICE technology appraisal guidance TA118
- [Bevacizumab in combination with oxaliplatin and either fluorouracil plus folinic acid or capecitabine for the treatment of metastatic colorectal cancer](#) (2010) NICE technology appraisal guidance TA212
- [Guidance on the use of capecitabine and tegafur with uracil for metastatic colorectal cancer](#) (2003) NICE technology appraisal guidance TA61
- [Capecitabine and oxaliplatin in the adjuvant treatment of stage III \(Dukes' C\) colon cancer](#) (2006) NICE technology appraisal guidance TA100
- [Radiofrequency ablation for colorectal liver metastases](#) (2009) NICE interventional procedure guidance IPG327
- [Selective internal radiation therapy for non-resectable colorectal metastases in the liver](#) (2013) NICE interventional procedure guidance IPG401
- [Microwave ablation for treating liver metastases](#) (2016) NICE interventional procedure guidance IPG553
- [Irreversible electroporation for treating liver metastases](#) (2013) NICE interventional procedure guidance IPG445
- [Cryotherapy for the treatment of liver metastases](#) (2010) NICE interventional procedure guidance IPG369
- [Preoperative high dose rate brachytherapy for rectal cancer](#) (2015) NICE interventional procedure guidance IPG531
- [Low energy contact X-ray brachytherapy \(the Papillon technique\) for early stage rectal cancer](#) (2015) NICE interventional procedure guidance IPG532
- [Suspected cancer: recognition and referral](#) (2015) NICE guideline NG12
- [Nutrition support for adults: oral nutrition support, enteral tube feeding and parenteral nutrition](#) (2006) NICE guideline CG32

- [Colorectal cancer prevention: colonoscopic surveillance in adults with ulcerative colitis, Crohn's disease or adenomas](#) (2011) NICE guideline CG118
- [Neutropenic sepsis: prevention and management in people with cancer](#) (2012) NICE guideline CG151

NICE guidance about the experience of people using NHS services

NICE has produced the following guidance on the experience of people using the NHS. This guideline will not include additional recommendations on these topics unless there are specific issues related to colorectal cancer:

- [Medicines optimisation](#) (2015) NICE guideline NG5
- [Patient experience in adult NHS services](#) (2012) NICE guideline CG138
- [Service user experience in adult mental health](#) (2011) NICE guideline CG136
- [Medicines adherence](#) (2009) NICE guideline CG76

3.5 Economic aspects

We will take economic aspects into account when making recommendations. For each review question (or key area in the scope) for which the evidence is being reviewed, we will develop an economic plan that states whether economic considerations are relevant, and if so whether this is an area that should be prioritised for economic modelling and analysis. We will review the economic evidence and carry out economic analyses, using an NHS and personal social services perspective, as appropriate.

3.6 Key issues and questions

While writing the scope for this updated guideline, we have identified the following key issues and key questions:

- 1 Prevention of colorectal cancer
 - 1.1 How effective is aspirin in the prevention of colorectal cancer in adults with clinical or genetic evidence of Lynch syndrome (hereditary nonpolyposis colorectal cancer)?
- 2 Molecular biomarkers

- 2.1 Does the use of molecular biomarkers to guide chemotherapy choice improve outcomes for people with colorectal cancer?
- 3 Management of local disease
 - 3.1 What is the most effective treatment for early rectal cancer?
 - 3.2 Which people with early colon cancer can be treated with endoscopic resection alone?
 - 3.3 Which people with localised colon cancer should receive preoperative chemotherapy?
 - 3.4 What is the effectiveness of preoperative radiotherapy or chemo radiotherapy for rectal cancer?
 - 3.5 Which people having neoadjuvant chemotherapy or chemoradiotherapy for rectal cancer do not need surgery?
 - 3.6 What is the optimal surgery for rectal cancer?
 - 3.7 What is the optimal duration of adjuvant chemotherapy for colorectal cancer?
 - 3.8 What is the effectiveness of stenting compared with emergency surgery for suspected colorectal cancer causing acute large bowel obstruction?
 - 3.9 What is the effectiveness of exenterative surgery for locally advanced or recurrent rectal cancer?
- 4 Management of metastatic disease
 - 4.1 Does surgery for the asymptomatic primary tumour improve outcomes for people with incurable metastatic colorectal cancer?
 - 4.2 What is the optimal combination and sequence of local and systemic treatments in patients presenting with metastatic colorectal cancer? In the:
 - Lung
 - Liver
 - Peritoneum
- 5 Ongoing care and support
 - 5.1 What are the optimal methods and frequencies of follow-up to detect recurrence after potentially curative surgical treatment for non-metastatic colorectal cancer?

5.2 What is the optimal management of post treatment sequelae (for example low anterior resection syndrome or chemotherapy related neurotoxicity)?

5.3 What are the information needs of people during and after treatment of colorectal cancer?

6 Service delivery

6.1 Is there a relationship between surgical volumes and outcomes in the treatment of rectal cancer (primary and recurrent disease)?

3.7 Main outcomes

The main outcomes that will be considered when searching for and assessing the evidence are:

- 1 Quality of life.
- 2 Overall survival.
- 3 Disease-free survival.
- 4 Progression free survival.
- 5 Treatment-related morbidity.
- 6 Treatment-related mortality.

4 NICE quality standards and NICE Pathways

4.1 NICE quality standards

NICE quality standards that may need to be revised or updated when this guideline is published

- [Colorectal cancer](#) (2012) NICE quality standard QS20

4.2 NICE Pathways

When this guideline is published, we will update the existing NICE Pathway on [colorectal cancer](#). NICE Pathways bring together everything NICE has said on a topic in an interactive flow chart.

5 Further information

This is the final scope, incorporating comments from registered stakeholders during consultation.

The guideline is expected to be published in October 2019.

You can follow progress of the [guideline](#).

Our website has information about how [NICE guidelines](#) are developed.