

NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

Guideline scope

Colorectal Cancer (update)

This guideline will update 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](#). We will also engage with stakeholder on areas that require updating.

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.

1 Colorectal cancer is the second most common cause of cancer death in the
2 UK, accounting for 10% of all deaths from cancer and approximately 16,000
3 deaths each year. Death rates have decreased by 42% overall since the early
4 1970s, with improvements each decade up to the present.

5 Survival rates continue to improve. Overall, 76% of people diagnosed with
6 bowel cancer live for at least 1 year, with 59% surviving at least 5 years and
7 57% for 10 years or more. Survival is linked to disease stage at presentation,
8 with improved survival the earlier the disease is detected and treated.

9 **Current practice**

10 ***Diagnosis and staging***

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

15 ***Local disease***

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

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

26 ***Metastatic disease***

27 Colorectal cancer is unusual among solid tumours in that metastatic spread to
28 the liver can still be cured with combinations of surgery and chemotherapy.
29 Recently, new chemotherapy drugs have been made available for metastatic
30 colorectal cancer with the RAS wild-type mutation following a NICE

1 technology appraisal. The chemotherapy pathways developed for the last
2 NICE guideline need to be updated to recognise these changes.

3 **2 Who the guideline is for**

4 People with suspected or diagnosed colorectal cancer, their families and
5 carers and the public will be able to use the guideline to find out more about
6 what NICE recommends, and help them make decisions.

7 This guideline is for:

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

13 It may also be relevant for:

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

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

23 ***Equality considerations***

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

- 26 • lists equality issues identified, and how they have been addressed
- 27 • explains why any groups are excluded from the scope.

1 The guideline will look at inequalities relating to:

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

5 **3 What the updated guideline will cover**

6 **3.1 Who is the focus?**

7 **Groups that will be covered**

- 8 • Adults (18 years and older) with newly diagnosed adenocarcinoma of the
9 colon.
- 10 • Adults with newly diagnosed adenocarcinoma of the rectum.
- 11 • Adults with relapsed adenocarcinoma of the colon.
- 12 • Adults with relapsed adenocarcinoma of the rectum.
- 13 • Adult carriers of Lynch syndrome [hereditary nonpolyposis colorectal
14 cancer (HNPCC)].

15 No specific subgroups of people have been identified as needing specific
16 consideration.

17 **Groups that will not be covered**

- 18 • People with anal cancer.
- 19 • Children and young people aged under 18 years with colorectal cancer.
- 20 • People with primary or secondary lymphoma of the colon and rectum.
- 21 • People with pure small cell carcinoma of the colon and rectum.
- 22 • People with neuroendocrine tumours of the colon and rectum.
- 23 • People with gastrointestinal stromal tumours (GIST) or sarcoma of the
24 colon and rectum.
- 25 • People with squamous cells carcinoma of the rectum.
- 26 • People with appendiceal neoplasms.

1 **3.2 Settings**

2 **Settings that will be covered**

- 3 • All settings in which NHS commissioned care is provided.

4 **3.3 *Activities, services or aspects of care***

5 **Key areas that will be covered in this update**

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

9 1 Prevention of colorectal cancer

- 10 – Role of aspirin in the prevention of colorectal cancer in carriers of
11 Lynch syndrome (hereditary nonpolyposis colorectal cancer)

12 2 Molecular biomarkers

- 13 - Use of molecular biomarkers to guide chemotherapy choice

14 3 Management of local disease

- 15 – Rectal cancer
- 16 – Colon cancer
- 17 – Colonic stents for obstructing colon cancer

18 4 Management of metastatic disease

- 19 – Presenting with stage IV colorectal cancer
- 20 – Methods for treating metastasis

21 5 Ongoing care and support

- 22 – Follow-up after apparently curative resection
- 23 – Management of post treatment sequelae
- 24 – Information about managing bowel function

25 6 Service delivery

- 26 – Surgical volumes and rectal cancer surgery

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

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

3 **Proposed outline for the guideline**

- 4 The table below outlines all the areas that will be included in the guideline. It
- 5 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 carriers 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	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 (2006) Recommendations 1.2.8.1-1.2.8.2 are based on NICE technology appraisal 100 (2006)
Colon cancer	
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 (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 included in 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 refer to section 6 of updated CG131 guideline for recommendations about palliative care

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2 Recommendations in areas that are being retained from the existing guideline
3 may be edited to ensure that they meet current editorial standards, and reflect
4 the current policy and practice context.

5 **Areas not covered by the guideline**

6 1 Population screening.

7 2 Colonoscopic surveillance of high-risk groups, including people with a
8 family history of colorectal cancer and people with inflammatory bowel
9 disease.

10 3 Management of anal cancer.

11 **3.4 Related NICE guidance**

- 12 • [Molecular testing strategies for Lynch syndrome in people with colorectal cancer](#) (2017) NICE guideline DG27
- 13
- 14 • [Virtual chromoendoscopy to assess colorectal polyps during colonoscopy](#)
- 15 (2017) NICE guideline DG28
- 16 • [Cetuximab and panitumumab for previously untreated metastatic colorectal cancer](#)
- 17 (2017) NICE technology appraisal guidance TA439
- 18 • [Trifluridine–tipiracil for previously treated metastatic colorectal cancer](#)
- 19 (2016) NICE technology appraisal guidance TA405
- 20 • [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](#)
- 21
- 22
- 23
- 24
- 25 (2012) NICE technology appraisal guidance TA242

- 1 • [Aflibercept in combination with irinotecan and fluorouracil-based therapy for](#)
2 [treating metastatic colorectal cancer that has progressed following prior](#)
3 [oxaliplatin-based chemotherapy](#) (2014) NICE technology appraisal
4 guidance TA307
- 5 • [Laparoscopic surgery for colorectal cancer](#) (2006) NICE technology
6 appraisal guidance TA105
- 7 • [Bevacizumab and cetuximab for the treatment of metastatic colorectal](#)
8 [cancer](#) (2012) NICE technology appraisal guidance TA118
- 9 • [Bevacizumab in combination with oxaliplatin and either fluorouracil plus](#)
10 [folinic acid or capecitabine for the treatment of metastatic colorectal cancer](#)
11 (2010) NICE technology appraisal guidance TA212
- 12 • [Guidance on the use of capecitabine and tegafur with uracil for metastatic](#)
13 [colorectal cancer](#) (2003) NICE technology appraisal guidance TA61
- 14 • [Capecitabine and oxaliplatin in the adjuvant treatment of stage III \(Dukes'](#)
15 [C\) colon cancer](#) (2006) NICE technology appraisal guidance TA100
- 16 • [Radiofrequency ablation for colorectal liver metastases](#) (2009) NICE
17 interventional procedure guidance IPG327
- 18 • [Selective internal radiation therapy for non-resectable colorectal](#)
19 [metastases in the liver](#) (2013) NICE interventional procedure guidance
20 IPG401
- 21 • [Microwave ablation for treating liver metastases](#) (2016) NICE interventional
22 procedure guidance IPG553
- 23 • [Irreversible electroporation for treating liver metastases](#) (2013) NICE
24 interventional procedure guidance IPG445
- 25 • [Cryotherapy for the treatment of liver metastases](#) (2010) NICE
26 interventional procedure guidance IPG369
- 27 • [Preoperative high dose rate brachytherapy for rectal cancer](#) (2015) NICE
28 interventional procedure guidance IPG531
- 29 • [Low energy contact X-ray brachytherapy \(the Papillon technique\) for early](#)
30 [stage rectal cancer](#) (2015) NICE interventional procedure guidance IPG532
- 31 • [Suspected cancer: recognition and referral](#) (2015) NICE guideline NG12
- 32 • [Nutrition support for adults: oral nutrition support, enteral tube feeding and](#)
33 [parenteral nutrition](#) (2006) NICE guideline CG32

- 1 • [Neutropenic sepsis: prevention and management in people with cancer](#)
2 (2012) NICE guideline CG151

3 **NICE guidance about the experience of people using NHS services**

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

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

12 **3.5 Economic aspects**

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

20 **3.6 Key issues and questions**

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

- 23 1 Prevention of colorectal cancer
 - 24 1.1 Is aspirin effective in the prevention of colorectal cancer in carriers of
25 Lynch syndrome (hereditary nonpolyposis colorectal cancer)?
- 26 2 Molecular biomarkers
 - 27 2.1 Does the use of molecular biomarkers to guide chemotherapy choice
28 improve outcomes for people with colorectal cancer?
- 29 3 Management of local disease
 - 30 3.1 What is the most effective treatment for early rectal cancer?

- 1 3.2 Which people with colon polyp cancer can be treated with
2 polypectomy alone?
- 3 3.3 Which patients with localised colon cancer should receive
4 preoperative chemotherapy?
- 5 3.4 What is the most effective preoperative radiotherapy or chemo
6 radiotherapy regimen for rectal cancer?
- 7 3.5 What is the effectiveness of a watch and wait policy compared to
8 surgery in patients following preoperative treatment in whom a complete
9 clinical response is achieved.
- 10 3.6 What is the optimal surgery for rectal cancer after preoperative
11 radiotherapy or chemoradiotherapy?
- 12 3.7 What is the optimal duration of adjuvant chemotherapy for colorectal
13 cancer?
- 14 3.8 What is the effectiveness of stenting followed by planned elective
15 bowel resection compared with emergency bowel resection for
16 suspected colorectal cancer causing acute large bowel obstruction?
- 17 4 Management of metastatic disease
- 18 4.1 What is the most effective first-line chemotherapy for people with
19 metastatic colorectal cancer (RASmutant)?
- 20 4.2 Does surgery for the asymptomatic primary tumour improve
21 outcomes for people with incurable metastatic colorectal cancer?
- 22 4.3 What is the optimal combination and sequence of local and systemic
23 treatments in patients presenting with oligometastatic colorectal cancer?
24 In the:
- 25 – Lung
- 26 – Liver
- 27 – Peritoneum
- 28 – Lymph nodes
- 29 5 Ongoing care and support
- 30 5.1 What are the optimal methods and frequencies of follow-up after
31 potentially curative surgical treatment for colorectal cancer (primary or
32 metastatic)?

- 1 5.2 What is the optimal management of post treatment sequelae (for
2 example low anterior resection syndrome or chemotherapy related
3 neurotoxicity)?
- 4 5.3 What are the information needs of people during and after treatment
5 of colorectal cancer?
- 6 6 Service delivery
- 7 6.1 Is there a relationship between surgical volumes and outcomes in
8 the treatment of rectal cancer (primary and recurrent disease)?

9 **3.7 Main outcomes**

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

- 12 1 Quality of life.
13 2 Overall survival.
14 3 Disease-free survival.
15 4 Progression free survival.
16 5 Treatment-related morbidity.
17 6 Treatment-related mortality.

18 **4 NICE quality standards and NICE Pathways**

19 **4.1 NICE quality standards**

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

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

23 **4.2 NICE Pathways**

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

1 5 Further information

This is the draft scope for consultation with registered stakeholders. The consultation dates are 3 August to 1 September 2017. [After consultation, delete this paragraph and replace it with 'This is the final scope, incorporating comments from registered stakeholders during consultation'.]

[Add this paragraph to public health topics only; delete for all others.] The final scope will take Public Health England priorities into account to ensure that associated areas of work carried out by the 2 organisations complement each other.

The guideline is expected to be published in February 2019.

You can follow progress of the [guideline](#). [Update the hyperlink with the in-development reference number.]

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

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