

**NATIONAL INSTITUTE FOR HEALTH AND CARE
EXCELLENCE**

HealthTech draft guidance

**Low-energy contact X-ray brachytherapy
for rectal cancer**

Rectal cancer is a type of cancer in the end part of the bowel, just above the anus. Symptoms include rectal bleeding, pain and changes in bowel habit, although the early stages may be asymptomatic. In this procedure, also known as the Papillon technique, an X-ray tube is inserted through the anus and into the rectum. The tube is placed in contact with the tumour and releases low-energy X-ray radiation (brachytherapy). The aim is to kill the cancer cells, shrink the tumour and reduce symptoms.

Guidance development process

NICE interventional procedures guidance evaluates procedures used for treatment or diagnosis. It provides evidence-based recommendations about how safe and effective these procedures are. The guidance supports healthcare professionals and commissioners to ensure that patients get the best possible care. By reviewing clinical evidence and considering patient outcomes, NICE aims to improve patient safety and treatment choices in the NHS.

Find out more on the [NICE webpage on interventional procedures guidance](#).

NICE is producing this guidance on low-energy contact X-ray brachytherapy for rectal cancer in the NHS in England. The interventional procedures advisory committee has considered the evidence and the views of clinical and patient experts.

This document has been prepared for consultation with the stakeholders. It summarises the evidence and views that have been considered and sets out the recommendations made by the committee. NICE invites comments from the stakeholders for this evaluation and the public. This document should be read along with the [evidence](#).

The committee is interested in receiving comments on the following:

- Has all of the relevant evidence been taken into account?
- Are the summaries of clinical effectiveness reasonable interpretations of the evidence?
- Are the recommendations sound and a suitable basis for guidance to the NHS?
- Are there any aspects of the recommendations that need particular consideration to ensure we avoid unlawful discrimination against any group of people on the grounds of age, disability, gender reassignment, pregnancy and maternity, race, religion or belief, sex or sexual orientation?

After consultation:

- Based on the consultation comments received, the committee may meet again.
- If committee meets again it will consider the evidence, this evaluation consultation document and comments from stakeholders.
- The committee will then prepare the final draft guidance, which will go through a resolution process before the final guidance is agreed.

Note that this document is not NICE's final guidance on low-energy contact X-ray brachytherapy for rectal cancer. The recommendations in section 1 may change after consultation.

More details are available in [NICE's interventional procedures programme manual](#).

Key dates

Closing date for comments: 23 July 2025

Second committee meeting: 11 September 2025

1 Recommendations

Early-stage and locally advanced rectal cancer

1.0 Low-energy contact X-ray brachytherapy can be used as an option to treat early-stage and locally advanced rectal cancer in people when either:

- the person chooses not to have surgery and their tumour:
 - is 3 cm or less and
 - has not spread beyond stage T3b or N1 (with limited nodal involvement), or
- surgery is not suitable.

People with larger tumours (with limited nodal involvement) may become eligible for this procedure if neoadjuvant treatment reduces the tumour to 3 cm or less.

Advanced rectal cancer

1.1 More research is needed on low-energy contact X-ray brachytherapy to treat advanced rectal cancer in people before it can be used in the NHS.

1.2 For people with advanced rectal cancer, this procedure should only be done as part of formal research and a research ethics committee needs to have approved its use.

What research is needed

More research, in the form of randomised controlled trials, in people with advanced rectal cancer is needed on:

- patient selection including tumour type and suitability for surgery
- treatment intent
- patient-reported outcomes
- survival
- organ preservation (the rectum and surrounding structures remain intact and functioning)
- quality of life
- long-term outcomes.

What this means in practice

Early-stage and locally advanced rectal cancer

There is enough evidence on the safety and efficacy of this procedure for clinicians to consider low-energy contact X-ray brachytherapy as an option for early-stage and locally advanced rectal cancer.

Clinicians should always discuss the available options with the person with rectal cancer before a joint decision is made (see [NICE's page on shared decision making](#)).

Hospital trusts will have their own policies on funding procedures and getting permission to do operations and monitoring results. NHS England may also have policies on funding of procedures.

Advanced rectal cancer

There is not enough evidence to know if this procedure is safe and effective for advanced rectal cancer. Low-energy contact X-ray brachytherapy should only be done as part of formal research.

Auditing of outcomes

Clinicians doing this procedure should collect data on safety and outcomes of the procedure. Enter details about everyone having this procedure into

the [ColoRectal database \(CR-DB\)](#) and regularly review the data on outcomes and safety.

Who should be involved in the procedure

Patient selection should be done by a colorectal cancer multidisciplinary team that includes a clinical oncologist and a colorectal surgeon with specific training in this procedure and expertise in local excision techniques. The procedure should only be done in centres specialising in managing rectal cancer.

Why the committee made these recommendations

Clinical trial evidence including randomised controlled trials and observational studies show that, in people with early-stage or locally advanced rectal cancer, low-energy CXB can achieve long-term disease control and is more likely to preserve the rectum and surrounding structures than surgery. Because radical surgery is avoided, patients may not need a permanent stoma. This substantially improves their quality of life.

For people with advanced rectal cancer, there is not enough evidence on the efficacy and safety of the procedure. So, it should only be done in research.

2 Information about the procedure

- 2.0 Low-energy contact X-ray brachytherapy (CXB) aims to improve local control or cure rectal cancer. The procedure involves inserting an X-ray tube through the anus and placing it in close contact with the tumour to kill cancer cells and reduce the size of the tumour. The tube emits low-energy X-rays that only penetrate a few millimetres, which minimises damage to deeper tissues.
- 2.1 Low-energy CXB for rectal cancer is usually delivered in an outpatient setting. The person having the procedure is given an enema before treatment to clear the bowel. During the procedure

they are in a knee-to-chest, prone jackknife (lying on their front, with hips flexed at a 90-degree angle so that their head and legs are lower than their hips) or supine (lying flat on their back) position. Local anaesthetic and glyceryl trinitrate are applied to the anal sphincter to numb the area and relax the sphincter muscles. A sigmoidoscope (a flexible tube with a camera and light that is used to look at the lower part of the large intestine, including the rectum) is inserted to check the size and position of the tumour. A rigid endorectal treatment applicator is then inserted and placed in contact with the tumour. A contact X-ray tube is placed into the applicator and treatment begins. . If the tumour does not respond to low-energy CXB or recurs after treatment, surgery may be performed.

- 2.2 Several different devices were used in the studies informing this guidance. All delivered a beam of 50-kV X-rays.

3 Committee discussion

The condition

- 3.1 Rectal cancer forms in the tissues of the rectum. The most common symptoms are rectal bleeding, pain and feeling like there is a lump in or around the anus. Less common symptoms include itching and changes to bowel habits. The likelihood of developing rectal cancer rises sharply with age.

Current practice

- 3.2 Management of rectal cancer depends on the disease stage and individual patient factors. Surgery has traditionally been the gold standard for early-stage rectal cancer, but radiotherapy or chemoradiotherapy with a 'watch and wait' approach is increasingly used. Advanced tumours are usually treated with surgery, such as transanal excision, endoscopic submucosal dissection or total mesorectal excision. If surgery is not suitable or the person

chooses not to have it, chemoradiotherapy may be used to shrink the tumour. [NICE's guideline on colorectal cancer](#) recommends preoperative radiotherapy or chemoradiotherapy for rectal cancer of stages cT1–T2, cN1–N2 and M0 or cT3–T4, any cN and M0. Radiotherapeutic options include external beam radiation therapy (EBRT) or brachytherapy, where radioactive material is placed inside or near the tumour.

Unmet need

- 3.3 Organ-preserving techniques and procedures have been increasingly adopted because they offer improvements in quality of life and reduce the risks and complications associated with surgery. So, they have become preferred by people with rectal cancer who do not wish to have surgery. One alternative to surgery, EBRT, is associated with skin discomfort as it is an external application of radiation. Low-energy CXB may provide a more targeted, organ-preserving option for local control. Also, low-energy CXB may be particularly beneficial for some people, such as older people with more comorbidities for whom surgery may not be an option.

The evidence

- 3.4 NICE did a rapid review of the published literature on the efficacy and safety of this procedure. This comprised a comprehensive literature search and detailed review of the evidence from 12 sources, which was discussed by the committee. The evidence included 1 systematic review and meta-analysis, 2 randomised controlled trials and 9 observational trials, and is presented in the summary of key evidence section in the interventional procedures overview. Other relevant literature is in the appendix of the overview.
- 3.5 The professional experts and the committee considered the key efficacy outcomes to be: quality of life, organ preservation, avoiding a permanent stoma, clinical response, survival and recurrence.

- 3.6 The professional experts and the committee considered the key safety outcomes to be: proctitis, rectal bleeding, mortality and dermatitis.
- 3.7 51 commentaries from people who have had low-energy CXB, or their carers were available. The committee highlighted the lived experience of people who have had this procedure, with every respondent stating that they would recommend it to other people with rectal cancer.

Committee comments

- 3.8 The committee noted that small polyps should be removed endoscopically as a first-line treatment, and that people with only small polyps would not be eligible for this procedure.
- 3.9 One of the clinical experts explained the opposing risk profiles of low-energy CXB and surgery. Low-energy CXB is less invasive but has a higher risk of local recurrence, while surgery offers more definitive control but carries greater upfront risks such as surgical complications and long-term side effects.
- 3.10 The committee noted that providing a less invasive option for treating rectal cancer may encourage people to use screening services.
- 3.11 The committee noted that people who have larger tumours (more than 3 cm) that have been reduced in size after neoadjuvant therapy and have limited nodal involvement may become eligible for this procedure.
- 3.12 The committee emphasised the importance of organ preservation (the rectum and surrounding structures) provided by low-energy CXB and its impact on quality-of-life outcomes.

- 3.13 The committee noted that regular ongoing surveillance is required for people who have this procedure, with repeat imaging and endoscopies recommended for 5 years after the procedure.

Equality considerations

- 3.14 The prevalence of rectal cancer is strongly related to age, with 75% of cases occurring in people aged 50 or over.
- 3.15 People from ethnic minority backgrounds are less likely to use screening services. This may lead to a delay in diagnosis and treatment.
- 3.16 The committee noted that there are only a few centres in the UK that specialise in managing rectal cancer and performing low-energy CXB. So, people living further from these centres may not have access to this procedure.

4 Committee members and NICE project team

This topic was considered by NICE's [interventional procedures advisory committee](#), which is a standing advisory committee of NICE.

Committee members are asked to declare any interests in the technology to be evaluated. If it is considered there is a conflict of interest, the member is excluded from participating further in that evaluation.

The [minutes of each committee meeting](#), which include the names of the members who attended and their declarations of interests, are posted on the NICE website.

Chair

Tom Clutton-Brock

Chair, interventional procedures advisory committee

NICE project team

Each evaluation is assigned to a team consisting of 1 or more health technology analysts (who act as technical leads for the evaluation), a technical adviser, a project manager and an associate director.

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