IP1724-2 Low-energy contact X-ray brachytherapy for rectal cancer

IPAC date: 11/09/2025

Com. no.	Consultee name and organisation	Sec. no.	Comments [sic]	Response Please respond to all comments
1	Consultee 1 Individual Oncologist	Not specified	In my view, all of the relevant evidence has been taken into account in the evaluation of this procedure. There is enough evidence on the safety and efficacy of this procedure for clinicians to make informed decisions. Organ-preserving techniques and procedures have been increasingly adopted in recent years, with low-energy contact X-ray brachytherapy emerging as the most powerful among them. The available data has been carefully reviewed, and due consideration appears to have been given to both the benefits and potential risks. As such, the conclusions drawn are well-supported, allowing for confidence in clinical practice and patient care.	Thank you for your comment
2	Consultee 2 ESTRO and RCR Clinical Oncologist	1.1 Early-stage and locally advanced rectal cancer	Suggested change-Is 3cm or less at the time of brachytherapy. Note the OPERA trial selected patients with tumour size <5cm	Thank you for your comment. Consultee suggests a change from 3cm or less to 5cm or less tumour size for procedure eligibility. The majority of the evidence used in the development of this guidance was

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				in tumours of 3cm or less. Therefore, there is currently not enough evidence in tumours above 3cm to support a 'can be used' recommendation. The device applicator cannot be used in tumours above 3cm, so guidance cannot be produced for tumours of this size. No change to guidance.
3	Consultee 2 ESTRO and RCR Clinical Oncologist	1.1 Early-stage and locally advanced rectal cancer	Surgery is not suitable-this is vague-do you mean the patient is at high risk from surgery or is medically unfit for surgery? Or do you also mean that surgery would require a permanent stoma and the patient wishes to avoid a permanent stoma?	Thank you for your comment. Change to section 1.1: The phrase *'surgery is not suitable'* has been replaced with the phrase *'when the risks of surgery are unacceptably high'*
4	Consultee 2 ESTRO and RCR Clinical Oncologist	1.1 Early-stage and locally advanced rectal cancer	In the section regarding larger tumours I would suggest that in addition to <3cm that you could put that the tumour is downstaged to yT3B or less since the extension beyond the muscular propria is also important in more bulky tumours	Thank you for your comment. Consultee suggests additional tumour staging criteria for people who have received treatment and achieved a reduction in tumour size. Section 1.1 has been updated to add the additional staging criteria *'it has*

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				not spread beyond stage T3b N1 M0' for people with larger tumours that have been reduced after neoadjuvant treatment.
5	Consultee 2 ESTRO and RCR Clinical Oncologist	1.1 Early-stage and locally advanced rectal cancer	What isn't clear here is that the majority of these patients should be receiving external radiotherapy +/- chemotherapy too. Papillon alone can be used in T1 patients who have had an ERUS to ensure the staging is correct and have no high-risk features	Thank you for your comment. Consultee suggests additional clarification regarding the use of external radiotherapy +/- chemotherapy. Neoadjuvant treatment is mentioned throughout the guidance and low-energy contact X-ray brachytherapy (CXB) is recommended as an 'option' to treat early stage and locally advanced rectal cancer. No change to guidance.
6	Consultee 2 ESTRO and RCR Clinical Oncologist	1.1 Advanced rectal cancer	There is ample prospective multi-centre evidence showing that adding a Papillon boost for high risk and surgically unfit patients and also surgical refusers with advanced cancer that has responded well to external beam radiotherapy gives favourable response rates and higher rates of control than expected with external radiotherapy alone. Therefore for these patients it would be important to treat within a registry (such as the	Thank you for your comment. Consultee suggests that patients with advanced rectal cancer should be given the option of treatment with low-energy CXB in the context of a registry, not necessarily a formal

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			Guildford database which regularly publishes combined outcomes such as those mentioned above) but seems unnecessary to place them in a formal clinical trial. Patients are currently able to access a watch and wait approach without being in a clinical trial if they achieve an unexpected complete or near complete clinical response with neo-adjuvant chemotherapy or external beam radiotherapy (for example the international watch and wait database used in UK centres). With the OPERA trial showing that a Papillon boost gives better control than external beam radiotherapy alone it would seem unfair to require the Papillon boost patients to enter a clinical trial whereas the external beam only patients are not in a trial and not even required to be in a database. As before if the tumour downstages to T3BN0 after neo-adjuvant treatment with diameter of 3cm or less then a Papillon boost would be appropriate for unfit or surgery refusing patients within a registry with appropriate counselling. Use of a registry rather than a clinical trial is also how the 2019 NICE guidance went forward and gained the data that is being assessed in this guidance	clinical trial as this may reduce access for this population. Consultee cites existing prospective evidence showing favourable responses to low-energy CXB in patients with advanced rectal cancer. The majority of the evidence used in the development of this guidance was in early-stage or locally advanced tumours of 3cm or less that have not spread beyond stage T3b N1 M0. Therefore, there is currently not enough evidence for the use of low-energy CXB in more advanced rectal cancer to recommend its use outside of formal research.
7	Consultee 2 ESTRO and RCR Clinical Oncologist	1.1 Advanced rectal cancer	What do you mean by advanced rectal cancer? It would be helpful to define this more precisely	Thank you for your comment. For the purposes of this guidance, early-stage and locally advanced is considered to be cancer that has not spread beyond stage T3b N1 M0. Committee discussed that tumour

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				staging criteria varies across the literature, and clinicians will use clinical judgement alongside the most recent evidence to assess cancer stage for each person they consider for this procedure. 'Advanced rectal cancer' has been amended to 'metastatic rectal cancer' in section 1.2. .
8	Consultee 2 ESTRO and RCR Clinical Oncologist	1.1 Advanced rectal cancer	You also haven't covered pretreatment here-patients who have had previous radiotherapy and have a new cancer or regrowth. This has been published and response rates are reasonable especially when surgery would be high risk or require removal of other organs such as the bladder	Thank you for your comment. Consultee suggests widening inclusion criteria to those who have had previous treatment and experienced a regrowth. The guidance does not specify that the procedure needs to be for the first tumour so this group is not excluded. No change to guidance.
9	Consultee 2 ESTRO and RCR	1.3 Advanced rectal cancer	If a patient has a small cancer and oligometastatic disease it could be quite appropriate to administer a Papillon boost and SABR to the metastasis and still	Thank you for your comment.

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	Clinical Oncologist		expect excellent long-term results. So possible metastatic disease should not be excluded	Consultee suggests widening inclusion criteria to patients who have treatable metastatic disease. There was not enough evidence to support a 'can be used' recommendation in this patient population. No change to guidance.
10	Consultee 2 ESTRO and RCR Clinical Oncologist	1.3 What research is needed	Patient reported outcomes and quality of life are the same thing	Thank you for your comment. Quality of life outcomes are a subset of patient reported outcomes. This has been clarified in the guidance. Wording change in 'What research is needed' section: patient-reported outcomes *(such as quality of life and functional outcomes)*
11	Consultee 2 ESTRO and RCR Clinical Oncologist	1.3 What research is needed	Long term outcomes-this is rather imprecise-you've mentioned QoL and survival and local control so what do you mean by this?	Thank you for your comment. This refers to any long-term outcome of interest not mentioned in the guidance.

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12	Consultee 2 ESTRO and RCR Clinical Oncologist	1.3 What research is needed	It should be recognised that funding must be provided for centres to enter data into a registry as this can be time consuming	Thank you for your comment. Consultee advises recognition of costs associated with maintaining a registry. This is not within the remit of the interventional procedures advisory committee. No change to guidance.
13	Consultee 2 ESTRO and RCR Clinical Oncologist	1.3 What research is needed	More research is required in the form of prospective registries and RCTs. We also need to know the role of total neoadjuvant therapy including systemic anti-cancer treatment.	Thank you for your comment. Consultee recommends additional research on total neoadjuvant therapy, including systemic anti-cancer treatment. 'What research is needed' section amended.
14	Consultee 2 ESTRO and RCR Clinical Oncologist	2.2 2 Information about the procedure	Is this level of procedural detail necessary? There are GEC ESTRO guidelines giving these details and centres may vary in their clinical delivery	Thank you for your comment. This guidance will also be read by people with the condition and non-medically trained members of the

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				public, therefore we want to provide as much detail as possible. No change to guidance.
15	Consultee 2 ESTRO and RCR Clinical Oncologist	2.2 2 Information about the procedure	The sigmoidoscope can be rigid or flexible	Thank you for your comment. Guidance amended.
16	Consultee 2 ESTRO and RCR Clinical Oncologist	3.1 The condition	Many patients have cancers which are asymptomatic and detected as a result of the national bowel cancer screening programme	Thank you for your comment. This has been added to the guidance. Additional wording for section 3.1: *For many people with the condition, the cancer is asymptomatic and detected through the national bowel cancer screening programme.*
17	Consultee 2 ESTRO and RCR Clinical Oncologist	3.2 Current practice	Advanced cancers are not treated with local excision or endoscopic submucosal excision-those are only used for early-stage cancer T1 in general	Thank you for your comment. Committee was informed that surgery is still used in some cases. No change to guidance.

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18	Consultee 2 ESTRO and RCR Clinical Oncologist	3.3 Unmet need	This paragraph does not read well as the majority of patients receive external radiotherapy in addition to brachytherapy. An alternative to surgery is radiotherapy. Radiotherapy requires high doses of radiation to the tumour to achieve cure. This can be difficult to achieve with external radiotherapy alone as it would result in more side effects. Therefore the addition of brachytherapy allows the radiation dose to be raised without a significant increase in toxicity	Thank you for your comment. Consultee clarifies that EBRT and low-energy CXB are often used in conjunction. Change to section 3.3: *When used with EBRT, low-energy contact X-ray brachytherapy (CXB) may provide a more targeted, organ-preserving option for local control by focusing radiation directly to the tumour without substantially increasing toxicity.*
19	Consultee 2 ESTRO and RCR Clinical Oncologist	Not specified	Please add ESTRO-European Society for Therapeutic Radiation Oncology-more specific that GEC-ESTRO which is the brachytherapy section of ESTRO, if we are allowed international organisations	Thank you for your comment. This has been added to the list of professional societies in the overview.
20	Consultee 2 ESTRO and RCR Clinical Oncologist	Not specified	Could also add British Institute of Radiology-BIR	Thank you for your comment. This has been added to the list of professional societies in the overview.
21	Consultee 3 Hull University Teaching	Not specified	I agree with the recommendations in this draft guidance and it will hopefully allow more patients with tumours < 3cm in size to have this treatment considered.	Thank you for your comment.

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	Hospitals NHS Trust Clinical Oncologist		I also agree more evidence is required for more 'advanced' cases. However, there are a group of patients with tumours > 3cm who show regression with external beam radiotherapy to < 3cm who could also benefit if either surgically unfit or stoma averse. The OPERA trial results in tumours > 3cm showed that with the addition of CXB about 2/3 patients achieved long term organ preservation. This failed to reach statistical significance as a result of a likely type 2 statistical error in view of the study closing early. Further research in this group and even more advanced tumours showing responses to initial external beam radiotherapy should be encouraged and supported as a matter of urgency and unmet need.	
22	Consultee 4 SurgEase Innovations Ltd	2.2 2 Information about the procedure	An alternative approach would be to use a video-assisted rigid sigmoidoscope which could provide opportunity for tumour assessment in an outpatient setting as opposed to a formal endoscopy suite.	Thank you for your comment. Change to section 2.2: '*video'* added to guidance.
23	Consultee 4 SurgEase Innovations Ltd	2.2 2 Information about the procedure	This could be done under direct view using a video-assisted rigid sigmoidoscope	Thank you for your comment. Please see response to comment 22.
24	Consultee 4 SurgEase	3.1 The condition	or if there is a familial genetic predisposition.	Thank you for your comment.

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	Innovations Ltd			Addition to section 3.1: *'or if there is a familial genetic predisposition'*
25	Consultee 4 SurgEase Innovations Ltd	3.13 Committee comments	The frequency of attendance to endoscopy may be reduced if a video-assisted rigid sigmoidoscope is used instead, which has been favoured by most patients trialling the service. The key advantage that it can be deployed in a clinic and often in an ambulatory setting.	Thank you for your comment. Please see response to comment 22. No other change to guidance.
26	Consultee 5 Royal Surrey NHS Trust Radiographer	2.2 2 Information about the procedure	Consider other analgesic options when required i.e Penthrox, mild sedation etc	Thank you for your comment. Addition to section 2.2: *'with or without sedation'*
27	Consultee 6 Mount Vernon Cancer Centre Clinical Oncologist	1 Early-stage and locally advanced rectal cancer	Some patients in this category may not need chemoradiotherapy at all if they proceed with surgical excision. It needs to be emphasized that an organ preservation route will potentially mandate chemoradiotherapy in some patients who did not need it if they had surgery, and this will come with associated risks and toxicities.	Thank you for your comment. Consultee suggests further clarification regarding trade-offs of foregoing TME in favour of organ-preserving interventions. This is covered in section 1.1 where it is stated that low-energy CXB can be used as an option to treat early-stage and locally advanced rectal cancer if the person **chooses not to** have

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				surgery or the risks of surgery are too high. It is important to advise people with the condition of this trade-off during consenting. No change to guidance.
28	Consultee 6 Mount Vernon Cancer Centre Clinical Oncologist	1.1 Early-stage and locally advanced rectal cancer	Guidance should caveat this statement with an emphasis on a comprehensive discussion on the pros/cons of contact RT in comparison to definitive surgery including risk of failure which has been the gold-standard for this setting, especially in higher risk patients with larger disease. The discussion should include both surgeon and oncologist. This discussion should also factor in why the patient is averse to surgery particularly in people with larger tumours and higher risk disease - and if these concerns can be addressed	Thank you for your comment. The importance of a cancer multidisciplinary team that includes a clinical oncologist and colorectal surgeon has been discussed in the 'What this means in practice' section. No change to guidance.
29	Consultee 6 Mount Vernon Cancer Centre Clinical Oncologist	3.1 Current practice	Guidance should link to practice regarding follow-up in those with organ preservation. This needs to consider modality of follow-up (clinical examination, MRI, endoscopy, rectoscopy), frequency of follow-up and management of toxicities etc.	Thank you for your comment. Consultee suggests further information be provided regarding patient follow-up after treatment with low-energy CXB. Modality and frequency of follow-up was discussed by committee and has been summarised in section 3.13.

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				No change to guidance.
30	Consultee 7 Barts Cancer Centre Clinical Oncologist	1.1 Early-stage and locally advanced rectal cancer	I would suggest in "neoadjuvant treatment" to add between brackets (external beam radiotherapy with or without concurrent chemotherapy).	Thank you for your comment. Change to section 1.1: People with larger tumours (with limited nodal involvement) may become eligible for this procedure if neoadjuvant treatment *(external beam radiotherapy with or without chemotherapy)* reduces the tumour to 3 cm or less and it has not spread beyond stage T3b N1 M0.
31	Consultee 7 Barts Cancer Centre Clinical Oncologist	1.3 What research is needed	Also, an area of research will be how to integrate CXB with neoadjuvant chemotherapy in the TNT era, were T3b and N1 lower rectal adenocarcinoma patients are currently eligible for neoadjuvant chemotherapy.	Thank you for your comment. The role of neoadjuvant therapy has been added as an outcome of interest in the 'What research is needed' section.
32	Consultee 7 Barts Cancer Centre Clinical Oncologist	1.3 Why the committee made these recommendations	Surgery does not aim to preserve the rectum and surrounding structures - I would change the sentence to "... is more likely to preserve the rectum and surrounding structures than neoadjuvant external beam radiotherapy with concurrent chemotherapy" which is what the OPERA study showed.	Thank you for your comment. Quality of life improvements and stoma avoidance in low-energy CXB were highlighted as important factors in committee decision-making. This wording can be clarified.

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				Amendment to 'Why committee made these recommendations' section: *low-energy contact X-ray brachytherapy can achieve long-term control of the condition while preserving the rectum and surrounding structures* .
33	Consultee 7 Barts Cancer Centre Clinical Oncologist	3.2 Current practice	Advanced tumours are rarely treated with transanal excision or endoscopic submucosal dissection, and TME is the gold standard. NICE does not recommend preoperative radiotherapy or chemoRT in T1-T2 N0, but in all stage III rectal cancer (this is T3 and above, and N1 or above). Current radiotherapy options only include EBRT and brachytherapy is currently only approved for non-operable patients (NICE 2013). Interstitial brachytherapy (radioactive material placed inside the tumour) is not current practice, nor has been approved.	Thank you for your comment. No change to guidance.
34	Consultee 7 Barts Cancer Centre Clinical Oncologist	3.3 Unmet need	Is not only that EBRT is associated with skin discomfort (this is only one of the potential effects of EBRT) is that EBRT alone (or in combination with chemotherapy) only achieves organ preservation in around 54% of patients (OPERA study, when combined with XELOX X 5 cycles as TNT). Hence, the use of CXB as a boost dramatically increases the organ preservation rates.	Thank you for your comment. Consultee suggests further clarification regarding the comparative efficacy of EBRT vs EBRT + CXB.

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				Change to section 3.3: '*skin discomfort'* has been replaced with '*a range of side-effects including skin discomfort'*. The organ preservation benefits associated with low-energy CXB have been mentioned elsewhere in the guidance. Therefore, it has not been added to section 3.3.
35	Consultee 7 Barts Cancer Centre Clinical Oncologist	3.15 Equality considerations	Also, some minority ethnic groups present with higher prevalence of stoma rejection.	Thank you for your comment. This has been added to the equality considerations section 3.17.
36	Consultee 8 Individual Clinical Oncologist	Not specified	It remains confusing: excluding advanced rectal cancers but allowing cancers that may still be T4N1 which downsize to <3cm after neoadjuvant therapy. There is no evidence from my reading that neoadjuvant therapy without radiotherapy currently has an evidence base and more research would be required for this. It would be good to stipulate that further research is required for tumours >3cm even if being permissive of eligibility outside of clinical trials. It should be stipulated this should only be made available where adequate follow up	Thank you for your comment. Consultee suggests further clarification regarding eligibility after tumour downsizing given the paucity of evidence for the procedure in this population.

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			is available and implemented for patients who would be deemed fit for salvage surgery	There is currently not enough evidence for the use of low-energy CXB in advanced rectal cancer to recommend its use outside of formal research. No change to guidance.
37	Consultee 9 East Suffolk Nort Essex Foundation Trust Clinical Oncologist	Not specified	Aim is organ preservation. There is increasing incidence of younger patients being diagnosed with early rectal cancer. Papillion treatment will provide an option that helps to improve the quality of life with excellent chances of cure. I believe its an area of unmet need, and the approval of this treatment in light of recent high quality research data, it will provide equality to access this treatment option .	Thank you for your comment
38	Consultee 10 Clinical Oncologist	Not specified	No comments but I agree with the recommendations	Thank you for your comment
39	Consultee 11 Radiographer	Not specified	No comments but I agree with the recommendations	Thank you for your comment
40	Consultee 12 General Surgeon	Not specified	No comments but I agree with the recommendations	Thank you for your comment

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