

NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

Health Technology Evaluation

Retifanlimab with platinum-based chemotherapy for treating inoperable, locally recurrent or metastatic squamous cell anal canal cancer untreated with systemic chemotherapy ID6482

Draft scope

Draft remit/evaluation objective

To appraise the clinical and cost effectiveness of retifanlimab within its marketing authorisation for treating inoperable, locally recurrent or metastatic squamous cell anal canal cancer untreated with systemic chemotherapy.

Background

Anal squamous cell carcinomas are a type of cancer which starts in the squamous cells that make up the lining of the anal canal and anal margin. The anal canal is the end portion of the large bowel. The anal margin is the edge of the anus; it can be partly seen as darker skin on the outside of the body. Cancer that starts in the anal canal and cancer that starts in the anal margin develop differently and so are treated differently.

Anal squamous cell carcinomas are the most common type of anal cancer, accounting for more than 80% of all anal cancers.¹ There were an estimated 1,600 new diagnoses of anal cancer each year in the UK (yearly average) from 2017 to 2019, of which two-thirds were in women.¹ The risk of developing anal cancer increases with age.² Around 20% of people diagnosed with stage 4 anal canal cancer are predicted to survive for 5 years or more following diagnosis.² The main risk factor for anal cancer is human papilloma virus (HPV) infection, which is linked to around 90% of anal cancers in the UK.² Symptoms of anal cancer include bleeding from the anus, pain or severe itching around the anal area, the sensation of a lump around the anus, and bowel changes.³

Treatment for anal cancer depends on the stage. The cancer may be removed with a local resection for stage 1, or with abdominoperineal resection if the cancer is in the anal canal and comes back after chemoradiotherapy.⁴ Chemoradiotherapy is standard treatment for stage 2 and 3 disease.⁵ The common chemotherapy combinations are mitomycin C with either fluorouracil or capecitabine.⁶ For inoperable anal canal cancer carboplatin plus paclitaxel or FOLFCIS (fluorouracil, folinic acid, and cisplatin) are used.⁷ Docetaxel may be included. Immunotherapy agents such as nivolumab, pembrolizumab, or retifanlimab are recommended as second-line options for cancer that progresses on chemotherapy and have not previously received immunotherapy.⁸

The technology

Retifanlimab (ZYNZY, Incyte Biosciences UK) does not currently have a marketing authorisation in the UK for treating inoperable, locally recurrent or metastatic squamous cell anal canal cancer untreated with systemic chemotherapy.

Draft scope for the evaluation of retifanlimab with platinum-based chemotherapy for treating inoperable, locally recurrent or metastatic squamous cell anal canal cancer untreated with systemic chemotherapy ID6482

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Page 1 of 4

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Retifanlimab in combination with carboplatin and paclitaxel is being studied in a clinical trial compared with carboplatin and paclitaxel and placebo in adults with locally advanced or metastatic squamous cell anal carcinoma.

Intervention(s)	Retifanlimab
Population(s)	Adult patients with inoperable locally recurrent or metastatic squamous cell carcinoma of the anal canal not previously treated with systemic chemotherapy
Comparators	Established clinical management without retifanlimab including, but not limited to: <ul style="list-style-type: none"> • Mitomycin C with either fluorouracil or capecitabine • Carboplatin and paclitaxel • Fluorouracil and cisplatin with folinic acid, or docetaxel • Cisplatin and capecitabine • Capecitabine and carboplatin
Outcomes	The outcome measures to be considered include: <ul style="list-style-type: none"> • overall survival • progression free survival • response rate • duration of response • adverse effects of treatment • health-related quality of life.
Economic analysis	<p>The reference case stipulates that the cost effectiveness of treatments should be expressed in terms of incremental cost per quality-adjusted life year.</p> <p>The reference case stipulates that the time horizon for estimating clinical and cost effectiveness should be sufficiently long to reflect any differences in costs or outcomes between the technologies being compared.</p> <p>Costs will be considered from an NHS and Personal Social Services perspective.</p> <p>The availability and cost of biosimilar and generic products should be taken into account.</p>

Other considerations	Guidance will only be issued in accordance with the marketing authorisation. Where the wording of the therapeutic indication does not include specific treatment combinations, guidance will be issued only in the context of the evidence that has underpinned the marketing authorisation granted by the regulator.
Related NICE recommendations	Related technology appraisals: Retifanlimab for treating anal canal squamous cell carcinoma after platinum-based chemotherapy [ID3815] Terminated Dec 2022

Questions for consultation

What is established clinical management for people with inoperable locally recurrent or metastatic squamous cell carcinoma of the anal canal not previously treated with systemic chemotherapy?

Where do you consider retifanlimab will fit into the existing care pathway for inoperable, locally recurrent or metastatic squamous cell anal canal cancer untreated with systemic chemotherapy?

Please select from the following, will retifanlimab be:

- A. Prescribed in primary care with routine follow-up in primary care
- B. Prescribed in secondary care with routine follow-up in primary care
- C. Prescribed in secondary care with routine follow-up in secondary care
- D. Other (please give details):

For comparators and subsequent treatments, please detail if the setting for prescribing and routine follow-up differs from the intervention.

Would retifanlimab be a candidate for managed access?

Do you consider that the use of retifanlimab can result in any potential substantial health-related benefits that are unlikely to be included in the QALY calculation?

Please identify the nature of the data which you understand to be available to enable the committee to take account of these benefits.

Please indicate if any of the treatments in the scope are used in NHS practice differently than advised in their Summary of Product Characteristics. For example, if the dose or dosing schedule for a treatment is different in clinical practice. If so, please indicate the reasons for different usage of the treatment(s) in NHS practice. If stakeholders consider this a relevant issue, please provide references for data on the efficacy of any treatments in the pathway used differently than advised in the Summary of Product Characteristics.

NICE is committed to promoting equality of opportunity, eliminating unlawful discrimination and fostering good relations between people with particular protected characteristics and others. Please let us know if you think that the proposed remit and scope may need changing in order to meet these aims. In particular, please tell us if the proposed remit and scope:

- could exclude from full consideration any people protected by the equality legislation who fall within the patient population for which retifanlimab will be licensed;
- could lead to recommendations that have a different impact on people protected by the equality legislation than on the wider population, e.g. by making it more difficult in practice for a specific group to access the technology;
- could have any adverse impact on people with a particular disability or disabilities.

Please tell us what evidence should be obtained to enable the committee to identify and consider such impacts.

NICE intends to evaluate this technology through its Highly Specialised Technologies Evaluation Programme. We welcome comments on the appropriateness of evaluating this topic through this process. (Information on NICE's health technology evaluation processes is available at:

<https://www.nice.org.uk/process/pmg36/chapter/introduction-to-health-technology-evaluation>).

References

1. Cancer Research UK (2025) [Anal cancer incidence statistics](#). Accessed 23 September 2025.
2. Cancer Research UK (2025) [Risks and causes of anal cancer](#). Accessed 23 September 2025.
3. Cancer Research UK (2025) [Anal cancer symptoms](#). Accessed 23 September 2025.
4. Cancer Research UK (2025) [Types of surgery for anal cancer](#). Accessed 23 September 2025.
5. Cancer Research UK (2025) [Treatment options for anal cancer](#). Accessed 23 September 2025.
6. Cancer Research UK (2025) [Chemotherapy for anal cancer](#). Accessed 23 September 2025.
7. Cancer Research UK (2025) [Treatment options for anal cancer | Cancer Research UK](#). Accessed 03 October 2025.
8. BMJ Best Practice (2025) [Anal cancer - Management Approach | BMJ Best Practice](#). Accessed 03 October 2025.