

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****Final scope****Remit/evaluation objective**

To appraise the clinical and cost effectiveness of retifanlimab in combination with carboplatin and paclitaxel within its marketing authorisation for treating inoperable, locally recurrent or metastatic squamous cell carcinoma of the anal canal (SCAC) 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. This appraisal will be focusing on squamous cell anal canal cancer.

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 Furthermore, anal cancer incidence rates in the UK are projected to increase by 14% between 2023–2025 and 2038–2040, with around 2,400 new cases each year by 2038–2040.² 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 and origin (e.g. anal margin or anal canal).³ Radiotherapy with concomitant mitomycin C, in combination with either 5-fluorouracil or capecitabine, is recommended as standard of care for localised SCAC (stages 1 to 3). Salvage surgery is considered for residual or locally recurrent disease after chemoradiotherapy.³ While the majority of localised SCAC do not require further treatment following chemoradiotherapy, approximately 20% develop local relapse³ for which salvage surgery is not always feasible. Recurrent disease not suitable for surgery and metastatic disease is treated with chemotherapy including carboplatin and paclitaxel.³ Other therapies may be used such as modified docetaxel, cisplatin, and 5-fluorouracil.

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

Issue Date: January 2026

© National Institute for Health and Care Excellence 2025. All rights reserved.

Page 1 of 3

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.

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 recurrent or metastatic squamous cell anal carcinoma.

Intervention(s)	Retifanlimab in combination with platinum-based chemotherapy
Population(s)	Adult patients with inoperable locally recurrent or metastatic squamous cell carcinoma of the anal canal not previously treated with systemic chemotherapy in the recurrent or metastatic setting
Comparators	Established clinical management without retifanlimab including, but not limited to: <ul style="list-style-type: none"> • Carboplatin and paclitaxel
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	The reference case stipulates that the cost effectiveness of treatments should be expressed in terms of incremental cost per quality-adjusted life year. 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. Costs will be considered from an NHS and Personal Social Services perspective. The availability and cost of biosimilar and generic products should be taken into account.

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: <u>Retifanlimab for treating anal canal squamous cell carcinoma after platinum-based chemotherapy [ID3815]</u> Terminated Dec 2022

References

1. Cancer Research UK (2025) [Anal cancer incidence statistics](#). Accessed 23 September 2025.
2. Cancer Research UK (2023). [Anal cancer statistics](#). Accessed 01 December 2025.
3. Rao S, Guren MG, Khan K, Brown G, Renehan AG, Steigen SE, et al. Anal cancer: ESMO Clinical Practice Guidelines for diagnosis, treatment and follow-up(☆). Ann Oncol. 2021;32(9):1087-100.