NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

Health Technology Appraisal

Retifanlimab for treating anal canal squamous cell carcinoma after platinum-based chemotherapy

Draft scope

Draft remit/appraisal objective

To appraise the clinical and cost effectiveness of retifanlimab within its marketing authorisation for treating anal canal squamous cell carcinoma after platinum-based 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[1]. The anal canal is the end portion of the large bowel[2]. The anal margin is the edge of the anus; it can be partly seen as darker skin on the outside of the body[2]. Cancer that starts in the anal canal and cancer that starts in the anal margin develop differently and so are treated differently[3].

Anal squamous cell carcinomas are the most common type of anal cancer, accounting for around 90% of all anal cancers[1]. There were an estimated 1,200 new diagnoses of anal cancer in England in 2017, of which two-thirds were in women[4]. The risk of developing anal cancer increases with age[5]. 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[5]. 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[6]. In 20% of cases of anal cancers, there are no symptoms[6].

For anal cancer, the most common treatment is chemoradiotherapy[7]. The chemotherapy drugs commonly used as part of this treatment are a combination of mitomycin and fluorouracil[8]. Other types of chemotherapy that may be used are platinum-based agents (cisplatin, oxaliplatin, carboplatin), irinotecan, capecitabine, bleomycin, lomustine, and paclitaxel[8]. If the cancer has not responded or returns after chemoradiotherapy, then a type of surgery called abdominoperineal resection may take place[7]. This removes the anus, rectum and part of the large bowel (colon)[9].

The technology

Retifanlimab (brand name unknown, Incyte Corp) is a human monoclonal antibody that targets a receptor on the surface of lymphocytes known as PD-1. This receptor is part of the immune checkpoint pathway and blocking its activity may promote an anti-tumour immune response. Retifanlimab is administered intravenously.

Retifanlimab does not currently have a marketing authorisation in the UK for treating anal canal squamous cell carcinoma after platinum-based chemotherapy. It has been studied in adults with anal canal squamous cell carcinoma in a clinical trial that has a single arm (that is, has no comparator).

Intervention(s)	Retifanlimab
Population(s)	Adults with anal canal squamous cell carcinoma
Comparators	• Abdominoperineal resection • Best supportive care
Outcomes	The outcome measures to be considered include: • overall survival • progression-free survival • response rates • 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 of any commercial arrangements for the intervention, comparator and subsequent treatment technologies will 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 and NICE Pathways	Related Quality Standards: Suspected Cancer (2016) NICE Quality Standard QS124
Related National Policy	The NHS Long Term Plan (2019). NHS Long Term Plan NHS England (2018). NHS manual for prescribed specialist services (2018/2019) Chapter 105, Specialist cancer services (adults) Department of Health and Social Care (2016). NHS Outcomes Framework 2016 to2017: Domains 1 and 2. Department of Health (2014). Improving Outcomes: A Strategy for Cancer, fourth annual report.

Questions for consultation

Which treatments are considered to be established clinical practice in the NHS for anal canal squamous cell carcinoma?

What treatments are available after platinum-based chemotherapy has failed?

Should abdominoperineal resection be included as a comparator?

Have all relevant comparators for retifanlimab been included in the scope?

How should best supportive care be defined?

Are the outcomes listed appropriate?

Are there any subgroups of people in whom retifanlimab is expected to be more clinically effective and cost effective or other groups that should be examined separately? 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.

Do you consider retifanlimab to be innovative in its potential to make a significant and substantial impact on health-related benefits and how it might improve the way that current need is met (is this a 'step-change' in the management of the condition)?

Do you consider that the use of retifanlimab can result in any potential significant and 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 Appraisal Committee to take account of these benefits.

To help NICE prioritise topics for additional adoption support, do you consider that there will be any barriers to adoption of this technology into practice? If yes, please describe briefly.

NICE intends to appraise this technology through its Single Technology Appraisal (STA) Process. We welcome comments on the appropriateness of appraising this topic through this process. (Information on the Institute's Technology Appraisal

processes is available at http://www.nice.org.uk/article/pmg19/chapter/1-Introduction).

References

1. Cancer Research UK (2019) Types of anal cancer. Accessed 16 April 2021.
2. Bowel Cancer UK (2018) Anal cancer. Accessed 13 May 2021.
3. BMJ Best Practice (2021) Anal cancer - symptoms, diagnosis and treatment. Accessed 13 May 2021.
4. Cancer Research UK (2019) Anal cancer incidence statistics. Accessed 16 April 2021.
5. Cancer Research UK (2020) Risks and causes. Accessed 16 April 2021.
6. Cancer Research UK (2019) Anal cancer symptoms. Accessed 16 April 2021.
7. Cancer Research UK (2019) Treatment decisions. Accessed 16 April 2021.
8. Cancer Research UK (2019) Chemotherapy treatment. Accessed 16 April 2021.
9. Cancer Research UK (2019) Types of surgery. Accessed 16 April 2021.