NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

Health Technology Appraisal

Rovalpituzumab tesirine for treating small-cell lung cancer after 2 therapies

Draft scope

Draft remit/appraisal objective

To appraise the clinical and cost effectiveness of rovalpituzumab tesirine within its marketing authorisation for treating small-cell lung cancer after 2 therapies.

Background

Lung cancer falls into two main histological categories: non-small-cell lung cancers and small-cell lung cancers. Small-cell lung cancer (SCLC) is a type of lung cancer that grows rapidly and spreads quickly to other parts of the body. SCLC can be classified as limited disease (cancer has not spread beyond the lung) or extensive disease (the cancer has spread beyond the lung)[1]. Common symptoms of SCLC include weight loss, malaise, bone pain, breathlessness and haemoptysis.

In 2015 there were 37,637 cases of lung cancer registered in England[2]. Around 12% of lung cancer cases are SCLC[1]. An estimated 58% of those with SCLC will receive first-line chemotherapy; of this group 95-100% will not respond or will ultimately relapse. Of the patients who relapse or do not respond, 40% will receive second line chemotherapy[3].

Following first treatment, CG121 recommends that people who are suitable for chemotherapy are treated with an anthracycline-containing regimen or further treatment with a platinum-based regimen to a maximum of six cycles. Radiotherapy can be offered for the palliation of local symptoms.

In addition, TA184 recommends oral topotecan as an option only for people with relapsed small-cell lung cancer for whom:

- Re-treatment with the first-line regimen is not considered appropriate and
- The combination of cyclophosphamide, doxorubicin and vincristine (CAV) is contraindicated.

The technology

Rovalpituzumab tesirine (brand name unknown, Abbvie) is a DLL3-targeted antibody-drug conjugate, which attaches to cancerous cells and releases a toxic component into the cell, causing it to die. It is administered intravenously.

Rovalpituzumab tesirine does not currently have a marketing authorisation in the UK treating small-cell lung cancer. It has been studied in a clinical trial with dexamethasone compared with placebo in adults with extensive-stage small-cell lung cancer after platinum-based therapy. It has also been studied as monotherapy in a single-arm trial for adults with DLL3-expressing small-cell lung cancer after 2 therapies.

Intervention(s)	Rovalpituzumab tesirine
Population(s)	People with small-cell lung cancer that has been treated with 2 therapies
Comparators	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 use of rovalpituzumab tesirine is conditional on the presence of DLL3. The economic modelling should include the costs associated with diagnostic testing for DLL3 in people with small-cell lung cancer who would not otherwise have been tested. A sensitivity analysis should be provided without the cost of the diagnostic test. See section 5.9 of the Guide to the Methods of Technology Appraisals.
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 technology appraisals: Topotecan for the treatment of relapsed small-cell lung cancer (2009). NICE technology appraisal 184. On static list. Technology appraisals in development: Lefitolimod maintenance treatment for small-cell lung cancer NICE technology appraisal guidance [ID1122]. Publication to be confirmed. Nivolumab with ipilimumab for previously treated extensive stage small-cell lung cancer NICE technology appraisal guidance [ID1228] Publication to be confirmed Related guidelines: Lung cancer: diagnosis and management (2011). NICE guideline CG121. Update in progress. Guidelines in development: Lung cancer: diagnosis and management (update). Publication expected January 2019. Related quality standards: Lung cancer in adults (2012) NICE quality standard 17. Related NICE Pathways: Lung cancer (2018) NICE Pathway.
Related National Policy	NHS England (2017) Manual for Prescribed Specialised Services 2017/18. Chapter 18 and 105. Department of Health, NHS Outcomes Framework 2016-2017 (published 2016): Domain 1. https://www.gov.uk/government/publications/nhs-outcomes-framework-2016-to-2017

Questions for consultation

Have all relevant comparators for rovalpituzumab tesirine been included in the scope? Which treatments are considered to be established clinical practice in the NHS for small-cell lung cancer after 2 therapies? How should best supportive care be defined?

Are the outcomes listed appropriate?

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

Where do you consider rovalpituzumab tesirine will fit into the existing NICE Pathway, lung cancer?

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 rovalpituzumab tesirine 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 rovalpituzumab tesirine 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 rovalpituzumab tesirine 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, Lung cancer: Stages, types and grades (Accessed December 2017)

2. Office for National Statistics (2017) Cancer Registration Statistics, England 2015 (Accessed December 2017)

3. National Institute for Health and Clinical Excellence (2009) Costing statement: topotecan for the treatment of small-cell lung cancer. Technology appraisal 184.