NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

Final draft guidance

Selpercatinib for advanced thyroid cancer with RET alterations after treatment with a cancer drug in people 12 years and over (managed access review of TA742)

1 Recommendations

- 1.1 Selpercatinib is recommended as an option in people 12 years and over for treating:
 - advanced RET fusion-positive thyroid cancer that is refractory to radioactive iodine (if radioactive iodine is appropriate), only if systemic therapy is needed after sorafenib or lenvatinib
 - advanced RET-mutant medullary thyroid cancer, only if systemic therapy is needed after cabozantinib or vandetanib.

Selpercatinib is only recommended if the company provides it according to the commercial arrangement (see <u>section 2</u>).

1.2 This recommendation is not intended to affect treatment with selpercatinib that was started in the NHS before this guidance was published. People having treatment outside these recommendations may continue without change to the funding arrangements in place for them before this guidance was published, until they and their NHS healthcare professional consider it appropriate to stop. For children or young people, this decision should be made jointly by the healthcare professional, the child or young person, and their parents or carers.

Final draft guidance – Selpercatinib for advanced thyroid cancer with RET alterations after treatment with a cancer drug in people 12 years and over (managed access review of TA742) Page 1 of 5

Why these recommendations were made:

This evaluation reviews the evidence for selpercatinib for treating advanced thyroid cancer with RET alterations (<u>NICE technology appraisal guidance 742</u>). It also reviews new data collected as part of the managed access agreement. The new evidence includes data from clinical trials and from people having treatment in the NHS in England.

This evaluation focuses on RET-mutant medullary thyroid cancer and RET fusionpositive thyroid cancer (thyroid cancer with RET alterations) after it has been treated with a targeted cancer drug (sorafenib, lenvatinib, cabozantinib or vandetanib).

Usual treatment for thyroid cancer with RET alterations that has been treated with a targeted cancer drug is best supportive care.

Clinical evidence suggests that people having selpercatinib have longer before their cancer gets worse, and live longer, than people having best supportive care. But selpercatinib was not directly compared with best supportive care, so these results are uncertain.

But when considering the condition's severity, and its effect on quality and length of life, the most likely cost-effectiveness estimates are within what NICE considers an acceptable use of NHS resources. So, selpercatinib is recommended.

For all evidence see the committee papers.

2 Information about selpercatinib

Anticipated marketing authorisation indication

2.1 Selpercatinib (Retsevmo, Eli Lilly) is expected to be indicated 'as monotherapy is indicated for the treatment of adults and adolescents 12 years and older with advanced RET-mutant medullary thyroid cancer and adults and adolescents with advanced RET fusion-positive thyroid cancer who are radioactive iodine-refractory (if radioactive iodine is appropriate)'.

Final draft guidance – Selpercatinib for advanced thyroid cancer with RET alterations after treatment with a cancer drug in people 12 years and over (managed access review of TA742) Page 2 of 5

Issue date: September 2024

© NICE [2024]. All rights reserved. Subject to Notice of rights.

2.2 <u>Selpercatinib is also being evaluated for advanced thyroid cancer with</u> <u>RET alterations untreated with a targeted cancer drug in people 12 years</u> <u>and over</u>.

Dosage in the marketing authorisation

2.3 The dosage schedule is available in the <u>summary of product</u> <u>characteristics for selpercatinib</u>.

Price

- 2.4 The list price is £2,184 for 56 capsules of 40 mg selpercatinib and £4,368 for 56 capsules of 80 mg (excluding VAT; BNF online accessed August 2024).
- 2.5 The company has a commercial arrangement (simple discount patient access scheme). This makes selpercatinib available to the NHS with a discount. The size of the discount is commercial in confidence.

3 Implementation

- 3.1 Section 7 of the <u>National Institute for Health and Care Excellence</u> (Constitution and Functions) and the Health and Social Care Information <u>Centre (Functions) Regulations 2013</u> requires integrated care boards, NHS England and, with respect to their public health functions, local authorities to comply with the recommendations in this evaluation within 3 months of its date of publication.
- 3.2 Chapter 2 of <u>Appraisal and funding of cancer drugs from July 2016</u> (including the new Cancer Drugs Fund) – A new deal for patients, taxpayers and industry states that for those drugs with a draft recommendation for routine commissioning, interim funding will be available (from the overall Cancer Drugs Fund budget) from the point of marketing authorisation, or from release of positive draft guidance, whichever is later. Interim funding will end 90 days after positive final guidance is published (or 30 days in the case of drugs with an Early Final draft guidance – Selpercatinib for advanced thyroid cancer with RET alterations after treatment with a

cancer drug in people 12 years and over (managed access review of TA742) Page 3 of 5

© NICE [2024]. All rights reserved. Subject to Notice of rights.

Access to Medicines Scheme designation or cost comparison evaluation), at which point funding will switch to routine commissioning budgets. The <u>NHS England Cancer Drugs Fund list</u> provides up-to-date information on all cancer treatments recommended by NICE since 2016. This includes whether they have received a marketing authorisation and been launched in the UK.

- 3.3 The Welsh ministers have issued directions to the NHS in Wales on implementing NICE technology appraisal guidance. When a NICE technology appraisal guidance recommends the use of a drug or treatment, or other technology, the NHS in Wales must usually provide funding and resources for it within 2 months of the first publication of the final draft guidance.
- 3.4 When NICE recommends a treatment 'as an option', the NHS must make sure it is available within the period set out in the paragraphs above. This means that, if a patient has advanced thyroid cancer with RET alterations and the healthcare professional responsible for their care thinks that selpercatinib is the right treatment, it should be available for use, in line with NICE's recommendations.

4 Evaluation committee members and NICE project team

Evaluation committee members

The 4 technology appraisal committees are standing advisory committees of NICE. This topic was considered by the lead team of <u>committee D</u>, which includes the vice chair.

Committee members are asked to declare any interests in the technology being evaluated. If it is considered there is a conflict of interest, the member is excluded from participating further in that evaluation.

Final draft guidance – Selpercatinib for advanced thyroid cancer with RET alterations after treatment with a cancer drug in people 12 years and over (managed access review of TA742) Page 4 of 5

Issue date: September 2024 © NICE [2024]. All rights reserved. Subject to Notice of rights.

Chair

Raju Reddy

Vice chair, technology appraisal committee D

NICE project team

Each evaluation is assigned to a team consisting of 1 or more health technology analysts (who act as technical leads for the evaluation), a technical adviser, a project manager and an associate director.

Emma McCarthy

Technical lead

Sally Doss Technical adviser

Celia Mayers Project manager

Jasdeep Hayre

Associate director

ISBN: [to be added at publication]

Final draft guidance – Selpercatinib for advanced thyroid cancer with RET alterations after treatment with a cancer drug in people 12 years and over (managed access review of TA742) Page 5 of 5

Issue date: September 2024

© NICE [2024]. All rights reserved. Subject to Notice of rights.