NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

Health Technology Evaluation

Oral paclitaxel with encequidar for treating advanced breast cancer

Draft scope

Draft remit/evaluation objective

To appraise the clinical and cost effectiveness of oral paclitaxel with encequidar within its marketing authorisation for treating advanced breast cancer.

Background

Breast cancer arises from the tissues of the ducts or lobules of the breast. 'Locally advanced' breast cancer generally refers to cancer that has spread from the breast to lymph nodes close to the breast, to the skin of the breast, or to the chest wall (stage 3). When the cancer has spread beyond the breast to other parts of the body such as the bones, liver, lung, and brain, it is known as advanced, or metastatic breast cancer (stage 4).

In 2019 in England, 48,387 people were diagnosed with breast cancer.[1] Approximately 4% of people with breast cancer in England in 2019 had stage IV (metastatic) breast cancer when they were diagnosed.[2] The 1-year survival rate for adults diagnosed at stage IV in England is 66%.[3] Around 35% of people with early or locally advanced disease will progress to metastatic breast cancer in the 10 years following diagnosis.[4]

Treatments for advanced breast cancer include chemotherapy and endocrine therapy (also known as hormonal treatment). Endocrine therapy is mainly given to people whose cancer is determined to be hormone-responsive, and is recommended as first line treatment for most people with advanced hormone receptor-positive breast cancer. Cyclin-dependent kinase (CDK) 4/6 inhibitors are recommended in NICE technology appraisals 495, 496 and 563, alongside hormonal treatment.

NICE clinical guideline 81 (CG81) recommends systemic sequential therapy for most patients with advanced breast cancer having chemotherapy. Where anthracyclines are not suitable (because they are contraindicated or because of prior anthracycline treatment) the sequencing should follow: single-agent docetaxel as a first-line treatment, single-agent vinorelbine or capecitabine as second line treatment, and single-agent capecitabine or vinorelbine (whichever was not used as second line treatment) as third line treatment. In addition, NICE technology appraisal 423 recommends eribulin as an option for treating locally advanced or metastatic breast cancer when it has progressed after at least two chemotherapy regimens.

The technology

Oral paclitaxel with encequidar (Oraxol, Athenex Inc). Paclitaxel is an anti-neoplastic agent which targets rapidly dividing cancerous cells. Encequidar is a gut-specific P-gp inhibitor. Paclitaxel and encequidar is administered orally.

© National Institute for Health and Care Excellence 2022. All rights reserved.

Appendix B

Oral paclitaxel with encequidar does not currently have a marketing authorisation in the UK for treating advanced breast cancer. It has been studied in a phase 3 clinical trial, compared with intravenous paclitaxel, in adults with advanced breast cancer for whom IV paclitaxel monotherapy has been recommended by their oncologist.

Intervention(s)	Oral paclitaxel with encequidar
Population(s)	People with advanced breast cancer for whom first line systemic chemotherapy is suitable.
Comparators	Intravenous docetaxel Intravenous paclitaxel
Outcomes	The outcome measures to be considered include: • response rate • progression-free survival • overall survival • 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. If the technology is likely to provide similar or greater health benefits at similar or lower cost than technologies recommended in published NICE technology appraisal guidance for the same indication, a cost comparison may be carried out. 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. 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.

© National Institute for Health and Care Excellence 2022. All rights reserved.

Related NICE recommendations	**Related Technology Appraisals:** Atezolizumab with nab-paclitaxel for untreated PD-L1-positive, locally advanced or metastatic, triple-negative breast cancer (2020) NICE technology appraisal guidance 639 **Related appraisals in development:** https://www.nice.org.uk/guidance/TA801 (2022). NICE technology appraisal guidance 801. **Related Guidelines:** Advanced breast cancer: diagnosis and treatment (2009 updated 2017) NICE guideline CG81 Early and locally advanced breast cancer: diagnosis and management (2018) NICE guideline NG101
Related National Policy	The NHS Long Term Plan, 2019. NHS Long Term Plan NHS England (2018/2019) NHS manual for prescribed specialist services (2018/2019)

Questions for consultation

Where do you consider oral paclitaxel with encequidar will fit into the existing care pathway for advanced breast cancer?

Which intravenous taxane-regimens are currently used as standard of care for this patient group?

Do you consider that the use of oral paclitaxel with encequidar 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.

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 oral paclitaxel with encequidar 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.

© National Institute for Health and Care Excellence 2022. All rights reserved.

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 Single Technology Appraisal process. We welcome comments on the appropriateness of appraising this topic through this process. (Information on NICE's health technology evaluation processes is available at https://www.nice.org.uk/about/what-we-do/our-programmes/nice-guidance/nice-technology-appraisal-guidance/changes-to-health-technology-evaluation).

NICE's health technology evaluations: the manual states the methods to be used where a cost comparison case is made.

- Would it be appropriate to use the cost-comparison methodology for this topic?
- Is the new technology likely to be similar in its clinical efficacy and resource use to any of the comparators?
- Is the primary outcome that was measured in the trial or used to drive the model for the comparator(s) still clinically relevant?
- Is there any substantial new evidence for the comparator technology/ies that has not been considered? Are there any important ongoing trials reporting in the next year?

References

1 NHS Digital (2022) Cancer registration statistics, England, 2019. Accessed May 2022.

2 Cancer Research UK (2022) Early diagnosis data hub. Accessed May 2022.

3 Cancer Research UK (2020) Breast cancer survival by stage at diagnosis: adults diagnosed 2013-2017, followed up to 2018. Accessed May 2022.

4 Dewis R and Gribbin J (2009) Breast cancer: diagnosis and treatment, an assessment of need. Cardiff: National Collaborating Centre for Cancer. Accessed May 2022.

© National Institute for Health and Care Excellence 2022. All rights reserved.