NICE National Institute for Health and Care Excellence

NICE guidance

Olaparib for treating BRCA mutation-positive HER2-negative advanced breast cancer after chemotherapy

Technology appraisal guidance
Published: 12 February 2025

www.nice.org.uk/guidance/ta1040

Your responsibility

The recommendations in this guidance represent the view of NICE, arrived at after careful consideration of the evidence available. When exercising their judgement, health professionals are expected to take this guidance fully into account, alongside the individual needs, preferences and values of their patients. The application of the recommendations in this guidance is at the discretion of health professionals and their individual patients and do not override the responsibility of healthcare professionals to make decisions appropriate to the circumstances of the individual patient, in consultation with the patient and/or their carer or guardian.

All problems (adverse events) related to a medicine or medical device used for treatment or in a procedure should be reported to the Medicines and Healthcare products Regulatory Agency using the Yellow Card Scheme.

Commissioners and/or providers have a responsibility to provide the funding required to enable the guidance to be applied when individual health professionals and their patients wish to use it, in accordance with the NHS Constitution. They should do so in light of their duties to have due regard to the need to eliminate unlawful discrimination, to advance equality of opportunity and to reduce health inequalities.

Commissioners and providers have a responsibility to promote an environmentally sustainable health and care system and should assess and reduce the environmental impact of implementing NICE recommendations wherever possible.

Contents

This guidance replaces TA762.

1 Recommendations

1.1 Olaparib is recommended, within its marketing authorisation, as an option for treating HER2-negative locally advanced or metastatic breast cancer with germline BRCA1 or BRCA2 mutations in adults who have had:

- an anthracycline and a taxane as neoadjuvant or adjuvant treatment, or for metastatic disease, unless these are not suitable, and
- endocrine therapy if they have hormone receptor (HR)-positive breast cancer, unless this is not suitable.

Olaparib is only recommended if the company provides it according to the commercial arrangement.

1.2 If people with the condition and their healthcare professional, after discussing the advantages and disadvantages of all the options, consider olaparib to be 1 of a range of suitable treatments, the lowest cost option should be used. Administration costs, dosages, price per dose and commercial arrangements should all be taken into account.

Why these recommendations were made

HER2-negative, locally advanced or metastatic breast cancer with germline BRCA1 or BRCA2 mutations is usually treated with an anthracycline and a taxane (chemotherapy). If the breast cancer is also HR positive, endocrine therapy with chemotherapy may also be used. Usual treatment after chemotherapy, and endocrine therapy if appropriate, is more chemotherapy or talazoparib.

Clinical trial evidence shows that people who have olaparib have longer before their cancer gets worse than people who have chemotherapy. Olaparib has not been directly compared with talazoparib in a clinical trial. But an indirect comparison suggests that it is likely to work as well as talazoparib.

A cost comparison suggests olaparib has similar or lower costs than talazoparib when all

relevant costs are taken into account including commercial agreements (see section 2). So olaparib is recommended.

For all evidence see the committee papers. For more information on NICE's evaluation of talazoparib, see the committee discussion section in NICE's technology appraisal guidance on talazoparib for treating HER2-negative advanced breast cancer with germline BRCA mutations.

Talazoparib is recommended for use after an anthracycline or a taxane, or both, which is a wider population than the licensed population for olaparib. A cost comparison of olaparib with talazoparib was suitable for this evaluation. This is because most people with the condition will have both an anthracycline and a taxane in line with NICE's guideline on early and locally advanced breast cancer. Clinical advice noted there is unlikely to be a difference in response to olaparib or talazoparib after previous treatment with an anthracycline or a taxane, or both.

2 Information about olaparib

Marketing authorisation indication

2.1 Olaparib (Lynparza, AstraZeneca) is indicated as 'monotherapy for the treatment of adult patients with germline BRCA1/2 mutations, who have HER2 negative locally advanced or metastatic breast cancer. Patients should have previously been treated with an anthracycline and a taxane in the (neo)adjuvant or metastatic setting unless patients were not suitable for these treatments. Patients with hormone receptor (HR) positive breast cancer should also have progressed on or after prior endocrine therapy, or be considered unsuitable for endocrine therapy'.

Dosage in the marketing authorisation

2.2 The dosage schedule is available in the summary of product characteristics for olaparib.

Price

2.3 The list price of olaparib is £2,317.50 per 56 pack of 150-mg tablets (excluding VAT, BNF online, accessed October 2024).

2.4 The company has a confidential commercial access agreement with NHS England. As part of this agreement, olaparib is available to the NHS with a discount. The size of the discount is commercial in confidence.

3 Implementation

3.1 Section 7 of the National Institute for Health and Care Excellence (Constitution and Functions) and the Health and Social Care Information Centre (Functions) Regulations 2013 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 90 days of its date of publication. Because olaparib has been recommended through the cost-comparison process, NHS England and integrated care boards have agreed to provide funding to implement this guidance 30 days after publication.

3.2 Chapter 2 of Appraisal and funding of cancer drugs from July 2016 (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 Access to Medicines Scheme designation or cost comparison evaluation), at which point funding will switch to routine commissioning budgets. The NHS England Cancer Drugs Fund list 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 HER2-negative locally advanced or metastatic breast cancer with germline BRCA1 or BRCA2 mutations and the healthcare professional responsible for their care thinks that olaparib 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 as a cost comparison evaluation by the lead team of the highly specialised technologies evaluation committee, which includes the chair and vice chair.

The chair and vice chair were asked to declare any interests for the evaluation of olaparib. If it is considered there is a conflict of interest, the member is excluded from participating further in that evaluation

Chair and vice chair

Dr Paul Arundel, Professor Iolo Doull
Chair and vice chair, highly specialised technologies evaluation committee

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.

Alice Bell
Technical lead

Samuel Slayen
Technical adviser

Jeremy Powell
Project manager

Emily Crowe

Associate director

ISBN: 978-1-4731-6848-0