# NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

## Final appraisal document

# Niraparib for maintenance treatment of relapsed, platinum-sensitive ovarian, fallopian tube and peritoneal cancer

## 1 Recommendations

1.1 Niraparib is recommended as an option for treating relapsed, platinum-sensitive high-grade serous epithelial ovarian, fallopian tube or primary peritoneal cancer that has responded to the most recent course of platinum-based chemotherapy in adults, only if:

- they have a BRCA mutation and have had 2 courses of platinum-based chemotherapy, or
- they do not have a BRCA mutation and have had 2 or more courses of platinum-based chemotherapy, and
- the company provides it according to the commercial arrangement.

### Why the committee made these recommendations

This appraisal reviews the additional evidence collected as part of the Cancer Drugs Fund managed access agreement for niraparib for maintenance treatment of relapsed, platinum-sensitive ovarian, fallopian tube and peritoneal cancer (NICE technology appraisal guidance 528).

Niraparib improves how long people with relapsed, platinum-sensitive ovarian, fallopian tube and peritoneal cancer live before their disease progresses. New evidence collected whilst niraparib was in the Cancer Drugs Fund suggests it may also extend how long these people live, although the survival benefit with niraparib for people without a BRCA mutation is uncertain.



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Cost-effectiveness estimates for niraparib in people with a BRCA mutation whose disease has responded to 2 courses of platinum-based chemotherapy and for people without a BRCA mutation whose disease has responded to 2 or more courses of platinum-based chemotherapy are in the range usually considered a cost-effective use of NHS resources. Therefore, niraparib is recommended.

# 2 Information about niraparib

## Marketing authorisation indication

2.1 Niraparib (Zejula, GSK) has a marketing authorisation for 'the maintenance treatment of adult patients with platinum-sensitive relapsed high grade serous epithelial ovarian, fallopian tube, or primary peritoneal cancer who are in response (complete or partial) to platinum-based chemotherapy'.

## Dosage in the marketing authorisation

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

## Price

2.3 The list price for niraparib is £4,500 for a 58-capsule pack of 100 mg capsules; £6,750 for an 84-capsule pack of 100 mg capsules (excluding VAT; British national formulary online, accessed August 2021)

2.4 The company has a commercial arrangement (simple discount patient access scheme). This makes niraparib available to the NHS with a discount. The size of the discount is commercial in confidence. It is the company's responsibility to let relevant NHS organisations know details of the discount.

# 3 Committee discussion

The appraisal committee considered evidence submitted by GSK, a review of this submission by the evidence review group (ERG), and responses from stakeholders. See the committee papers for full details of the evidence.

## Treatment pathway and clinical need

### There is an unmet clinical need for maintenance treatments in clinical practice, especially for people without a BRCA mutation

3.1 Relapsed ovarian, fallopian tube or peritoneal cancer is a devastating condition with limited treatment options. For people who have had fewer than 3 courses of platinum-based chemotherapy, there are no maintenance treatment available. People have multiple cycles of chemotherapy as the disease responds and relapses. The patient expert explained that chemotherapy side effects can substantially reduce a patient's quality of life and concerns about relapse and the need for repeated courses of treatment is physically and psychologically challenging. NICE recommends olaparib for maintenance treatment of relapsed platinum-sensitive ovarian, fallopian or peritoneal cancer for people with a BRCA1 or BRCA2 mutation who have had 3 or more courses of platinum-based chemotherapy. Niraparib and olaparib are both poly-ADP-ribose polymerase (PARP) inhibitors. The clinical expert explained that maintenance therapy with PARP inhibitors can delay disease progression and extend the time between platinum-based chemotherapies. Delaying disease progression may therefore delay the onset of platinum drug resistance. People with ovarian cancer that becomes platinum resistant have fewer chemotherapy regimen options available when the disease relapses and therefore have a poor prognosis. So, treatments that avoid the need for chemotherapy are highly valued by patients and their families. Extending survival, even by only a few months can give people valuable extra time with family and friends. The clinical experts explained that several PARP inhibitors are currently available for

first-line use through the Cancer Drugs Fund (see technology appraisal guidance 598, technology appraisal guidance 693 and technology appraisal guidance 673) for people with and without a BRCA mutation, but are limited to only niraparib in people without a BRCA mutation. The committee acknowledged that 80% of people with ovarian cancer do not have a BRCA mutation and that there is particularly high unmet need in this group because no PARP inhibitors are recommended in routine commissioning after second line treatment. The clinical expert also explained that because PARP inhibitors would not be used more than once in the treatment pathway, the number of people who would have treatment in a relapsed disease setting may be smaller in future clinical practice (depending on future Cancer Drug Fund reviews). The committee concluded that there is an unmet need for maintenance treatments in clinical practice, especially for people without a BRCA mutation.

## Clinical evidence

### Niraparib improves progression-free survival compared with placebo regardless of how it is assessed

3.2 The clinical-effectiveness evidence came from NOVA, a double-blind, randomised, placebo-controlled trial. NOVA assessed the clinical effectiveness of niraparib in people with relapsed, platinum-sensitive ovarian cancer, with and without a BRCA mutation. Patients had previously had 2 or more platinum-based chemotherapy regimens and their cancer had responded to the last regimen. In the original NICE technology appraisal guidance, niraparib showed statistically significantly improved progression-free survival compared with placebo for both subgroups (with and without a BRCA mutation). However, the effect of niraparib on overall survival was uncertain. It was concluded that more mature data from NOVA could resolve this uncertainty and provide more evidence on the relative treatment effect. More data from NOVA has now been collected, and was analysed in October 2020. This analysis included an additional 53 months of data compared with the original appraisal.

There was no updated data on progression-free survival because it was not assessed after the primary analysis. The committee recalled:

- The median progression-free survival in people without a BRCA mutation was 9.3 months with niraparib and 3.9 months with placebo. The difference in median progression-free survival between niraparib and placebo was 5.4 months (hazard ratio [HR] 0.45, 95% confidence interval [CI] 0.34 to 0.61; p<0.001).
- For people with a BRCA mutation, median progression-free survival was 21 months with niraparib and 5.5 months with placebo. The difference in median progression-free survival was 15.5 months (HR 0.27, 95% CI 0.17 to 0.41; p<0.001).

The committee noted that progression-free survival results differed based on how they were assessed. The committee were aware that the company model used progression free survival results assessed by an Independent Review Committee (IRC). The committee noted that any difference in benefit accrued could have a significant impact on the cost effectiveness results because time on treatment (and so the related cost) was based on investigator assessment (IA), the preferred assumption from the original appraisal of niraparib. The ERG explained that this could result in costs and benefit not being aligned in the economic modelling. The committee considered the results of the 2 alternative methods of assessing progression free survival (IA or IRC). Results are considered confidential and cannot be reported here. The committee noted niraparib increased progression-free survival compared with placebo in both treatment groups using both assessments. Both assessments showed greater clinical benefit in people with a BRCA mutation although the size of benefit was smaller for progression-free survival assessed by IA. The clinical expert and Cancer Drugs Fund clinical lead cautioned focusing only on the median results and explained that the hazard ratios of both IA and IRC assessed progression-free survival were similar. The committee agreed that, because hazards were similar regardless of who assessed,

the method of assessment was unlikely to be critical to decision making. In response to the appraisal consultation document, the company prepared scenario analyses exploring the effect of using progression free survival assessed by IA. These showed that results were not substantially different from results using IRC. The difference in median progression free survival with the 2 assessment methods was less pronounced for people without a BRCA mutation and the committee concluded that the progression free survival assessed by IA was not critical for decision making in this subgroup. Therefore, niraparib improves progression-free survival compared with placebo, regardless of how it is assessed.

## Niraparib may improve overall survival compared with placebo for people with a BRCA mutation but survival benefit with niraparib for people without a BRCA mutation is highly uncertain

3.3 The committee recalled that median overall survival had not been reached in the original appraisal of niraparib and that survival benefit with niraparib was the main clinical uncertainty. Updated data from NOVA showed:

- Median overall survival in people without a BRCA mutation was 31.1 months with niraparib and 36.5 months with placebo. The difference in median overall survival between niraparib and placebo was 5.4 months (HR 1.1, 95% CI 0.83 to 1.46).
- Results for people with a BRCA mutation are confidential and cannot be reported.

The committee noted that NOVA was not powered to test for statistical significance for overall survival and the company and ERG explained that the results for the placebo arm are confounded by a high rate of subsequent PARP inhibitor use and missing data. Discontinuation from the trial was more than 80% in both niraparib and placebo arms with at least 14% missing data. As a result, only updated survival data from the niraparib arm of NOVA was used for assessment of relative effectiveness. The committee noted that despite high levels of subsequent PARP

inhibitor use in NOVA the company had not attempted to adjust for this in their submission using methods such as the inverse probability of censoring weighting adjustment (IPCW). The committee was aware that a recent commentary from a presentation at the Society of Gynecologic Cancer conference showed this analysis was available for a previous data cut from the NOVA trial. The clinical expert and Cancer Drugs Fund clinical lead both agreed that the progression-free survival benefit shown for niraparib is likely to translate into an overall survival benefit for people with a BRCA mutation. The evidence was less certain for those without a BRCA mutation. In response to the appraisal consultation document, the company presented results adjusting for subsequent PARP inhibitor use in both people with and without a BRCA mutation. It highlighted the high discontinuation rate from both trial arms (see section 3.2) and considered that the IPCW results were not suitable for decision making because the amount of missing data meant subsequent PARP inhibitor treatment status was unknown for many people in the trial (25% incomplete) and there was also incomplete survival follow up. The ERG noted that, where data were available, cross over appeared to be limited (13%) for people in the placebo group who did not have a BRCA mutation and that the IPCW adjusted results were similar to unadjusted results. However, they cautioned that the analyses needed assumptions about the imputation of missing data. The committee concluded that niraparib may improve overall survival for people with a BRCA mutation but survival benefit with niraparib for people without a BRCA mutation is highly uncertain. Further analyses adjusting for cross-over to subsequent treatments are inconclusive and are not able to resolve the uncertainty.

## Estimating relative effectiveness of niraparib compared with routine surveillance should be based on analyses adjusted for differences in baseline characteristics between NOVA and Study 19

3.4 Because of limitations in the survival data from the placebo arm of NOVA, the company used alternative data sources to estimate the relative

effectiveness of niraparib compared with routine surveillance. In their original Cancer Drug Fund review submission, the company used an assumption of a progression-free survival to overall survival benefit ratio of 1:1 to estimate overall survival for people on routine surveillance as their base case. For this appraisal, they also presented 2 alternative scenario analyses, one using placebo data from the olaparib trial, Study 19, and a second using routine surveillance data from UK real world evidence published by Lord et al. 2020. The ERG preference was to use a naive comparison of niraparib data from NOVA with data from Study 19 for the routine surveillance arm. Study 19 is a double-blind, placebo-controlled, international multicentre randomised controlled trial designed to assess the safety and efficacy of olaparib in people with platinum-sensitive recurrent ovarian or fallopian tube cancer or primary peritoneal cancer with high grade serous features or a serous component. After technical engagement, the company revised its base case to use Study 19 data in alignment with the ERG. The committee noted there were differences in the patient characteristics between the subgroups in NOVA and Study 19 and that no adjustments had been attempted by the company to account for these differences. To account for the high uncertainty in the results of the naive comparison with Study 19 to estimate relative effectiveness of niraparib compared with routine surveillance, the company did an anchored matched adjusted indirect treatment (MAIC) comparison for people without a BRCA mutation. Adjusted data from NOVA compared with Study 19 using weighted statistical analyses showed limited differences in results between MAIC adjusted niraparib overall survival data from NOVA and naive comparison of niraparib data from NOVA with Study 19 routine surveillance arm. The committee concluded that using the MAIC analysis to estimate the relative effectiveness of niraparib compared with routine surveillance had limitations but was the best source of data available.

## The overall trial population in NOVA is not suitable for decision making

3.5 The ERG noted that the company reported results for the overall trial population, that is, presented combined data for people with and without a BRCA mutation from NOVA. The company highlighted that the pooled population is aligned with the marketing authorisation for niraparib and that it allows survival outcomes of patients treated with niraparib to be compared with the UK-based, real-world evidence. Lord et al. 2020 published survival outcomes of people treated with standard care across 13 National Health Service trusts. This study included patients who had completed at least 2 lines of platinum-based chemotherapy with evidence of an objective disease response (complete or partial response), similar to people enrolled in NOVA. BRCA mutation status was unknown for most people in the study (84.5%), so results were not available by BRCA status. The clinical expert explained that although both people with and without a BRCA mutation could have niraparib, clinical trial evidence suggests considering these groups separately because prognosis is different for each subgroup. The committee concluded that the overall trial population is not suitable for decision making and that the subgroups of interest in this appraisal are people with a BRCA mutation who have had 2 lines of platinum-based chemotherapy or people without a BRCA mutation who have had 2 or more lines of platinum-based chemotherapy.

## Data from the systemic anti-cancer therapy (SACT) database is less relevant than updated data from NOVA

3.6 Observational data for patients in the Cancer Drugs Fund from the SACT dataset was presented by the company but were not originally included in its economic analysis. SACT data was collected for people with a BRCA mutation whose disease had responded to 2 courses of platinum-based chemotherapy and people without a BRCA mutation whose disease had responded to 2 or more courses of platinum-based chemotherapy. In the December 2019 data cut, 43% (n=68) of people with a BRCA mutation and 59% (n=509) of people without a BRCA mutation had completed

treatment, that is, patients had stopped treatment because of progression, acute toxicity, patient choice, or death, or because the patient did not have a treatment record entered in SACT in at least 3 months. Median follow up for overall survival was 20.3 months and 17.5 months for people with a BRCA mutation and people without a BRCA mutation, respectively. Median overall survival was not reached for people with a BRCA mutation, but the survival rates show that 87% were alive at 12 months, and 64% at 24 months. For people without a BRCA mutation, median overall survival was 22.6 months. The ERG highlighted that differences seen between SACT and NOVA results are likely to be because of differences between patient populations. The committee was aware that no comparator data is available from the SACT dataset. It considered alternative data sources for the comparator treatment arm such as the Study 19 placebo arm and Lord et al. 2020. The committee recalled that the observational data are not split by BRCA status (see section 3.6) and so did not consider it suitable for decision making. The ERG explained that using Study 19 placebo arm data would be comparing RCT data with non-randomised data which may underestimate the relative efficacy of niraparib because of the high heterogeneity in the patient populations. In response to the appraisal consultation document, the company reiterated that overall survival data for niraparib from SACT compared with overall survival data for the routine surveillance arm of Lord et al. 2020 provides an important real-world evidence comparative analysis to reduce uncertainty in the overall survival benefit with niraparib. Results from SACT and the Lord et al. 2020 scenario analyses show that cost-effectiveness estimates using a variety of data sources are within a similar range or less than the company's updated base case. The ERG did not consider the analyses were robust because of limitations in a naive comparison between non-randomised real-world sources and randomised data. They noted that prognosis is often better in a clinical trial setting that in clinical practice and the scenario comparing Lord et al. 2020 with the SACT intention-to-treat population is not relevant because it does not provide clinical- or

cost-effectiveness estimates for people with or without a BRCA mutation separately (the populations of interest in this appraisal, see section 3.5). The committee agreed that although subgroup data from NOVA may not be fully reflective of NHS clinical practice, it is still the source of the most mature and robust data for niraparib. The committee concluded that data from the SACT database is less useful for decision making than updated data from NOVA.

## Cost effectiveness

### The company's updated model is suitable for decision making

3.7 The committee considered the preferred committee assumptions from the original appraisal of niraparib. It recalled that variation in the cost-effectiveness estimates was largely dependent on choice of survival curves to model progression-free survival and ratio of the progression-free survival to overall survival benefit used to estimate overall survival. The committee in the original appraisal of niraparib had concluded that there was a plausible potential for niraparib to be cost effective, and that updated survival data from NOVA could reduce the uncertainty and produce more reliable cost-effectiveness estimates using the original economic model. It had accepted the company's means-based model, noting that the choice of model structure was not critical to decision making, because the company had explored other model structures such as the partitioned survival model and stated that results did not differ by much. The ERG considered the company's means-based model structure to be inappropriate now that mature survival data from NOVA is available and considered that a partitioned survival model should be used to validate results of the company model. The committee agreed that a partitioned survival model would be more suitable considering mature overall survival data is available. It would have preferred that the company's original partitioned survival model was validated by the ERG and the impact of model structure on the updated results explored.

However, on balance the committee concluded that that the company's updated means-based model was suitable for decision making.

### The company's approach to modelling survival is suitable for people with a BRCA mutation

3.8 The committee recalled that the progression-free survival data was unchanged for this Cancer Drug Fund review but that the terms of engagement outline that survival modelling should consider both statistical and visual fit of parametric and flexible spline models for modelling progression-free survival data and for the company to fully investigate the most appropriate overall survival modelling using updated clinical trial data. After technical engagement, for people with a BRCA mutation the ERG and company agreed on using the same survival curves to extrapolate progression-free (a flexible hazard k=1 curve) and overall survival (lognormal distributions) to extrapolate data from Study 19 for the routine surveillance arm and updated overall survival data from NOVA for the niraparib arm.The committee recalled their conclusion that there was progression free survival benefit with niraparib in this subgroup (see section 3.2) and a possible benefit in overall survival (see section 3.3). It agreed that the approach used by the ERG and company to model survival was suitable. The committee noted it would have preferred to see adjustments for cross over and baseline characteristics for people with a BRCA mutation but that these analyses were unlikely to affect the cost effectiveness results significantly. The committee concluded that the company's approach to modelling survival is suitable for people with a BRCA mutation whose disease has responded to 2 courses of platinum-based chemotherapy.

### The extrapolation of progression-free survival for people without a BRCA mutation is not critical to decision making

3.9 The company used a flexible normal k=1 curve to estimate progression-free survival beyond the trial period for people without a BRCA mutation. The ERG preferred a more conservative curve (flexible hazard k=1) which

was considered more clinically plausible. The committee noted that the estimates from the two curves were almost identical but that the company's normal k=1 had a better statistical fit. The committee also noted that the long-term estimates from the hazard k=1 curve were more aligned with subgroup of people with a BRCA mutation from 15 years onwards. The committee concluded that the choice between these extrapolations of progression-free survival for people without a BRCA mutation is not critical to decision making.

**Estimating overall survival for people without a BRCA mutation using data from Study 19 for routine surveillance is reasonable**

3.10 The company had agreed with the ERG's preferred approach to estimate overall survival for routine surveillance after technical engagement. They agreed to use overall survival data from Study 19 for the routine surveillance arm and updated overall survival data from NOVA for the niraparib arm (see section 3.4). Analyses provided in response to the appraisal consultation document accounting for crossover to PARP inhibitors (see section 3.3) and adjusting for differences in baseline characteristics (see section 3.4) showed that adjusted overall survival results were similar to the unadjusted results. The committee accepted that estimating overall survival for people without a BRCA mutation using data from Study 19 for the routine surveillance arm presented the most robust source for comparative data. In response to the committee's request for a conservative scenario assuming no overall survival benefit for people without a BRCA mutation, the company highlighted that the assumption of a gain in progression free survival resulting in zero overall survival gain is not clinically plausible. It noted that this was supported by trial evidence for maintenance therapies in advanced relapsed ovarian cancer and that a 1:1 progression free survival to overall survival ratio should be the minimum survival benefit with niraparib compared with routine surveillance. The committee concluded that estimating overall survival for people without a BRCA mutation using data from Study 19 for

routine surveillance which results in a survival benefit for people without a BRCA mutation is reasonable.

### The extrapolation of time to treatment discontinuation is not critical to decision making and the company's estimates are reasonable

3.11 The company and the ERG had different approaches to modelling time to treatment discontinuation. The company applied a log-logistic distribution for people without a BRCA mutation and applied a cap to the modelling so it could not exceed progression free survival. The company noted this was the best fitting distribution based on AIC and BIC statistics as well as visual inspection and better reflected the long-term SACT data. The ERG explained that the loglogistic curve underestimates the tail of the Kaplan–Meir curve, which could underestimate the costs of niraparib. It considered the Gompertz curve provided a more conservative assumption for costs of niraparib. The committee concluded that the company's estimation of time to treatment discontinuation was more reflective of clinical practice and therefore the most appropriate.

### Treatment specific utility values are appropriate for decision making

3.12 The company used treatment-specific utility values based on mapped EQ-5D-3L data from NOVA in its original submission for niraparib. For the Cancer Drug Fund submission, the company updated the treatment-specific utility values using the later 2020 data cut from NOVA. The company noted that these utilities reflected a higher quality of life on niraparib compared with routine surveillance. The higher utility values may reflect lower symptom burden from previous chemotherapy. The ERG preferred health-state utilities based on progression status because it did not think that niraparib would be associated with better health-related quality of life because the adverse event rate was higher for niraparib compared with placebo. The clinical expert and Cancer Drugs Fund clinical lead noted that utilities may improve on niraparib as it may improve clinical response for people with partial response to treatment. The company explained that niraparib has a positive effect on the mental

health of patients having an active treatment that delays progression of disease instead of a "wait and watch" approach. They noted that this benefit was not captured in the trial data because of the double-blind nature of NOVA and was not incorporated in the utilities and economic model. A linear mixed effects regression showed differences in the mean utility scores statistical difference between treatment arms after controlling for health state. The committee noted that using progression-based utility values caused the cost-effectiveness estimates to increase but concluded that treatment specific utility values are appropriate for decision making.

**The dose of niraparib may be lower in clinical practice and this is reflected using the company's treatment dose estimates**

3.13 The company amended the mean cost for niraparib based on updated dose data from the latest NOVA data-cut (the company used the prescribed dose in the original appraisal of niraparib). The dose used by the company in the Cancer Drug Fund review was based on actual dose consumed (dispensed dose minus returned dose per cycle) and reflected treatment doses returned by patients to the investigator during the trial. In its original appraisal, the committee preferred to use the prescribed dose as a weighted average. The committee considered that prescribed niraparib doses are unlikely to be returned to the NHS and reused. In response to the appraisal consultation document, the company agreed that prescribed doses are unlikely to be returned in clinical practice but considered that unused doses can be used in subsequent cycles with minimal wastage. It also highlighted that the niraparib dose used in economic model reflects actual dosage used in NOVA. All patients in NOVA started treatment on 300 mg of niraparib daily as per the summary of product characteristic. The clinical expert explained that clinicians favour starting treatment with a lower 200 mg daily dose of niraparib in clinical practice because it is associated with reduced toxicity and treatment stopping rates. The company explained that the NORA clinical trial which used lower doses showed equal efficacy to the NOVA study and results are therefore expected to be sustained and similar to the

300 mg daily higher dose in clinical practice. The committee noted that the company produces 100 mg capsules to account for this change in clinical practice and concluded that actual dose data for niraparib from NOVA is appropriate to use in the economic model.

## Cost-effectiveness results

### The incremental cost-effectiveness ratios are within the range considered a cost-effective use of NHS resources

3.14 The committee recalled that the company's model was suitable for decision making (see section 3.7) and the company's base-case assumptions were reasonable for decision making. The company's incremental cost-effectiveness ratios (ICERs) for people with a BRCA mutation was £22,185 per quality-adjusted life year (QALY) gained. Following the second appraisal committee, the company updated its commercial arrangement for people without a BRCA mutation. The ICER for this population was then within the range normally considered to be a cost-effective use of NHS resources (£20,000 to £30,000 per QALY gained). The committee concluded that niraparib could be recommended for routine commissioning for maintenance treatment of relapsed, platinum-sensitive ovarian, fallopian tube and peritoneal cancer for people with a BRCA mutation whose disease has responded to 2 courses of platinum-based chemotherapy and for people without a BRCA mutation whose disease has responded to 2 or more courses of platinum-based chemotherapy.

# 4 Implementation

4.1 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 clinical commissioning groups, NHS England and, with respect to their public health functions, local authorities to comply with the recommendations in this appraisal within 3 months of its date of publication.

4.2 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 fast track appraisal), at which point funding will switch to routine commissioning budgets. The NHS England and NHS Improvement 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.

4.3 The Welsh ministers have issued directions to the NHS in Wales on implementing NICE technology appraisal guidance. When a NICE technology appraisal 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 appraisal document.

4.4 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 relapsed, platinum-sensitive ovarian, fallopian tube and peritoneal cancer and the doctor responsible for their care thinks that niraparib is the right treatment, it should be available for use, in line with NICE's recommendations.

# 5 Review of guidance

5.1 The guidance on this technology will be considered for review 3 years after publication. The guidance executive will decide whether the

technology should be reviewed based on information gathered by NICE, and in consultation with consultees and commentators.

Brian Shine
Chair, appraisal committee
February 2022

# 6 Appraisal committee members and NICE project team

## Appraisal committee members

The 4 technology appraisal committees are standing advisory committees of NICE. This topic was considered by committee A.

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

The minutes of each appraisal committee meeting, which include the names of the members who attended and their declarations of interests, are posted on the NICE website.

## NICE project team

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

**Sana Khan**
Technical lead

**Lorna Dunning**
Technical adviser

**Thomas Feist**
Project manager

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